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ABSTRACT

This report is a summary of the findings from the Subcommittee on Health and Long-Term Care of the United States House of Representatives Select Committee on Aging investigation of cataract surgery and the use of intraocular lenses (IOL's) in the United States. The document provides background on the definition and treatment of cataracts and describes IOL implantation procedures, the IOL industry in the United States and abroad, and IOL utilization, including numbers and costs. Medicare payment for cataract surgery is also examined. Current problems are detailed, including efficacy and safety; cost; kickbacks, discounts, and rebates; and no cost advertisements. Results from surveys of ophthalmologists and the IOL industry regarding their experiences with fraud, waste, and abuse in the area of cataract surgery are analyzed and a conversation with an IOL salesman is reported. Current regulatory activity involving IOL enforcement, approval, and reimbursement is detailed. Policy recommendations, based on the findings, are listed and supported by the conclusion that cataract surgery is fraught with fraud, waste, and abuse but can still be provided with some improvements in program administration and legislative changes. A glossary of terms specific to the cataract industry and an anatomy of the eye are included. Several appendices present surveys of ophthamologists and the IOL industry, information supplied by the Food and Drug Administration and the Health Care Financing Administration, and marketing materials of the IOL industry. (ABB)

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[COMMITTEE PRINT]

CATARACT SURGERY: FRAUD, WASTE, AND ABUSE

A REPORT

BY THE

CHAIRMAN

OF THE

SUBCOMMITTEE ON HEALTH AND LONG-TERM CARE

OF THE

SELECT COMMITTEE ON AGING HOUSE OF REPRESENTATIVES

NINETY-NINTH CONGRESS

FIRST SESSION

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JULY 19, 1985

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FOREWORD

In 1983, the Subcommittee on Health and Long-Term Care of the U.S. House Select Committee on Aging undertook the first Congressional investigation of cataract surgery in the United States. This report is the summary of the Subcommittee's findings. In sum, the Subcommittee found that there is widespread fraud, waste, and abuse in cataract surgery — the most frequently reimbursed major surgical procedure in the United States today.

The Subcommittee concluded that over $2 billion that we will spend in 1985 for cataract surgery will be lost to fraud, waste, and abuse, and that this surgical procedure, from the taxpayer's perspective, is an unmitigated disaster. In order that the more than 1,000,000 older Americans might reap the benefits of vision attributed to this uncontested miraculous procedure, the Subcommittee urges immediate reform measures to address this hidden, yet prevalent problem.

The Chairman's report was prepared at the direction of Kathleen Gardner Cravedi, Staff Director of the Subcommittee and written by her and Peter Reinecke, Research Director, Glen Stettin, National Health Policy fellow, Medical College of Pennsylvania, Melanie Modlin, Deputy Staff Director, Ronald Schwartz, Office of the Inspector General for the Department of Health and Human Services, and Catharine Wilson, intern, Duke University who also tabulated, analyzed and summarized information supplied the Subcommittee by ophthalmologists, the industry and others. Eve Subrin, intern, Cornell University graduate, Liz Gatti, intern, Duke University, Bob Joy, detail, U.S. Postal Service, and Hal Wallach, detail, U.S. General Accounting Office, also provided valuable assistance to the Subcommittee — without whom this report would not be possible. The Subcommittee also recognizes the consulting services of Bill Halamandaris and Jay Constantine whose policy insights were invaluable from the inception of this Subcommittee investigation. The Subcommittee also wishes to commend numerous others whose counsel during the investigation helped balance the many issues explored.

I commend this report to all those concerned with preventing the abuses we uncovered. I hope it will lead this Nation to much needed reform.

Claude Pepper, Chairman

EXECUTIVE SUMMARY

CATARACT SURGERY: FRAUD, WASTE, AND ABUSE

In 1982, a Congressional inquiry revealed massive, fraud, waste, and abuse in the purchase and use of pacemakers in the Medicare program. Investigators uncovered a pervasive, industry-wide practice of kickback schemes, overutilization and profiteering in the pacemaker industry at the expense of Medicare and the taxpayer.

During the course of the pacemaker investigation, a representative of one of the manufacturers told a consultant to the Committee, then posing as a prospective purchaser for a California hospital, that these practices were not limited to the sale and use of pacemakers. "In addition, he said,"we sell intraocular lenses, heart valves, orthopedic devices, and health products for seniors. We have great flexibility. We (the distributor) give. They (the manufacturer) gives. We can even work out a package deal. We can arrange at least a 15% discount on VA approved prices." (The Veterans Administration purchases pacemakers, lenses and other medical equipment at a competitive bid process which commonly runs 15-20% lower than Medicare's payments for the same products.)

The salesmen went on to indicate that intraocular lenses in particular were a profitable product, saying anyone, including the hospital administrator, could learn how to perform the implant procedure and that it could be done on an outpatient basis or "almost anywhere."

When he learned of this conversation in 1983, Chairman Pepper instructed the Subcommittee to undertake a thorough investigation of cataract surgery and the use of intraocular lenses (IOLs) in the United States. This report is the result of that activity.

During this investigation, the Subcommittee undertook the following steps:

- Collected, reviewed and tabulated correspondence and case histories received by the Subcommittee relating to cataract surgery since 1983.
- Reviewed all hearings and reports on fraud and abuse in the Medicare program by Congressional Committees and administrative agencies.
- Prepared and sent a questionnaire to a statistically valid random sample of ophthalmologists in the United States at the Chairman's request. The responses to these questions were tabulated and appear later in this report. The questionnaire can be found in Appendix A of this report.
- Prepared and sent a questionnaire to all IOL manufacturers on file with the U.S. Food and Drug Administration. The responses to these questions were tabulated and appear later in this paper. The questionnaire can be found in Appendix B.
- Conducted telephone surveys with numerous IOL representatives, associations representing ophthalmologists, health industry representatives and concerned doctors.
- Reviewed all books, periodicals, and newspaper references to cataract surgery and Medicare reimbursement policies on file with the Library of Congress.
- Prepared and sent questionnaires to the U.S. Food and Drug Administration and the Health Care Financing Administration. The responses to these questions were incorporated into this report. The questionnaires can be found in Appendices C and D respectively.
- Requested and obtained a staff member from the Office of the Inspector General of the United States, Department of Health and Human Services, to assist the Subcommittee in its investigation.
- Called upon the Office of the Inspector General to undertake an investigation into the billing and reimbursement practices for cataract surgery in the United States.
- Called upon the General Accounting Office to conduct a review of Medicare reimbursement practices to determine regionally what Medicare pays for cataract surgery.

- Interviewed numerous sales representatives for the IOL industry, ophthalmologists, association representatives, enforcement officials, health and medical experts.

The Subcommittee found that cataract surgery is the most frequently reimbursed major surgical procedure reimbursed by the Medicare program today. Intraocular lenses (IOLs), the replacement of choice following cataract surgery, will be implanted in 1 million of the 1.2 million people who will have cataract surgery in 1985. The total cost of these cataract procedures will exceed $3.5 billion. $3.03 billion of that total will be paid for by Medicare. The Subcommittee found that there is reason to question the necessity or validity of half of that total. 50 cents of every dollar Medicare pays for this procedure is lost either to fraud, waste, or abuse. The factors forcing this conclusion are as follows.

Cataract surgery, which in 1981 required a 3-day stay in a hospital, now requires a 3-hour visit to a hospital on an outpatient basis. About 70% of all cataract surgery is performed today in the outpatient setting of a hospital. Improved surgical techniques and hospital cost containment have contributed largely to the shift from the hospital to the outpatient setting for cataract surgery. Intuitively, one would think that savings would accrue to the Medicare program by eliminating hospital stays and the attendant services which accompany the stay. This has not been the case. Medicare pays no less than $2400 for cataract surgery performed in the hospital where the costs are controlled by the new DRG system. When the same procedure is performed in the same hospital on an outpatient basis, Medicare is paying several times this amount — as much as $5700 — for using only three hours of hospital resources. While the DRG system was intended to reduce Medicare costs by putting a limit on the amount paid for services provided in a hospital, the same rules do not apply to outpatient services, or part B of Medicare. The Subcommittee found that if the Medicare program reimbursed all cataract surgery at the inpatient rate of $2400, regardless of surgical setting, a savings of at least $1.2 billion would be realized in 1985, and a total of almost $9 billion by 1990. Given current reimbursement practices, Medicare will waste $1.2 billion in 1985 alone.

Another factor fueling fraud, waste, and abuse in cataract surgery relates directly to the price of the IOL and Medicare reimbursement practices relating to the IOL. In 1984, the price of an IOL reimbursed by the Medicare program ranged from $322 to $750. The manufacturing cost for an IOL is roughly $35-$50. Under the DRG system many hospitals have gone to competitive bidding, reducing IOL prices by 50% or more, sometimes less than $100 a piece. Where outpatient surgery is performed, there is no corresponding pressure to reduce IOL prices as mentioned above because Medicare will pay what it terms "reasonable" cost ranging from about $300 to $750 or more. It is obvious that the profit margins are very high and that some manufacturers are trying to stave off true competitive bidding by taking $50-$150 or more out of their profits to "buy off" some physicians and gain a competitive edge.

The Subcommittee found that evidence of improper inducements, kickbacks, and other illegal marketing practices is flagrant and inescapable. Inducements ranged from outright payments of cash to physicians (in the form of $50 deposits in Cayman Islands accounts) for each lens purchased, to "free stock" in the manufacturer, "free lasers" and other IOL surgery equipment, "donations" of one lens for every one purchased, keys to resort condominiums, yachts, cars and houses, trips to Colorado, Europe, etc. for "medical" skiing seminars, and large payments for phony consultant work and to FDA "investigators". Large donations to the physician's favorite charity or personal research foundations by IOL representatives were also uncovered. Our investigation confirmed the judgment of one physician who told the Subcommittee, "The whole system is corrupt and is corrupting physicians, mostly I feel, out of ignorance — but of course greed is a big factor. Some very big names in ophthalmology are receiving large financial incentives to PR the companies' implants. I'm happy to see you investigating this and though it casts a shadow on my profession — if we can stop the 20% or so who are unethical it may restore people's faith in my profession."

Over one million IOLs, manufactured by about 20 companies in the United States, will be implanted in 1985, costing on the average almost $400 apiece. Medicare will pay for approximately 816,000 of these implants, totalling about $325 million. Out of those 20 companies, the Subcommittee found only several companies who were making a conscientious effort to avoid illegal practices. Evidence suggests that about half the price of each lens is lost to fraud and improper inducements resulting in a loss to the Medicare program in 1985 of about $160 million.

Finally, leading health and medical experts have reported that 23%-36% of all cataract surgery may be unnecessary or represent overutilization, and that second opinions should be sought by those considering such surgery. Many Americans may show signs of cataracts but have no functional inpairment. It is at this point in the decision

process that unnecessary surgery may occur. In some cases, this decision is simply a matter of poor judgment on the part of the physician. In other cases, however, the Subcommittee found instances where doctors in one southern state were inserting IOLs into the eyes of elderly patients with 20-20 vision. About $819 million will be lost to the Medicare program and cataract patients due to unnecessary surgery in 1985. Of this total, $525 million will be lost by the Medicare program alone.

Section I of this report provides the definition of cataracts and treatment methods for correcting this disabling disease. In addition, the costs and reimbursement mechanisms for this surgery are detailed, as are the numbers served and the industry which exists to meet this population's needs.

Cataracts will affect almost everyone who lives long enough. About 15 million persons over age 65 have some signs of cataracts today. Fortunately, the method for treating cataracts is unquestionably successful and frequently administered — over one million surgical procedures correcting the complications of cataracts will be performed in the U.S. in 1985 at a cost to the government and the taxpayer of $3.5 billion — making cataract procedures the most frequently performed major surgical procedure reimbursed by the Medicare program today.

Section II of this report discusses the problems surrounding cataract surgery which include waste, fraud, and abuse. The Subcommittee also found costs associated with the surgery and Medicare reimbursement practices are excessive — resulting in a loss to the government and taxpayer of about $2 billion annually; and that a number of regulatory and industry practices, if left unchecked, will continue to fuel widespread fraud, waste and abuse.In addition, the Subcommittee found that at least 25% of such surgery may be unnecessary.

Sections III and IV describe data collected from ophthalmologists and IOL manufacturers from which the Subcommittee was able to reach the following conclusions:

- The majority of ophthalmologists surveyed told the Subcommittee that they were aware of abusive practices in the marketing of IOLs.
- Inducements to use certain IOLs were common and included the purchase of second homes, cash payments, free equipment, stock in the company and free travel, among others.
- The majority of ophthalmologists told the Subcommitee that such offers are commonplace and should not be encouraged.
- Many manufacturers do not like the sales tactics the Subcommittee has found prevalent in the IOL industry.

Section V is a candid conversation between an ophthalmologist and an IOL salesman. It details an offer of free business equipment in exchange for doing business exclusively with a particular IOL manufacturer.

Section VI discusses Federal action with respect to cataract surgery in the United States, and Section VII includes a number of policy options for the consideration of the Congress and the consumer:

- The Health Care Financing Administration should take measures to control outpatient costs associated with cataract surgery;
- The Health Care Financing Administration should standardize payment for cataract surgery;
- The Food and Drug Administration should take immediate action to eliminate "adjunct" studies; and
- Seniors should seek second opinions before pursuing cataract surgery.

What this report concludes is that the Government and the taxpayer will continue to lose about 50 cents of every dollar they pay for cataract surgery unless corrective action is taken. What is not discussed but implicit in this report is the extent to which the health and welfare of every patient, who is usually elderly, will be forsaken as the result of current practices that remain unchecked.

INTRODUCTION

Cataract surgery. This is a common operation for persons over the age of 65 — for if one lives long enough, one will probably get a cataract and require such surgery. In the United States today, a person living a normal lifespan is more likely to undergo a cataract operation than any other major surgical procedure. Over 15 million older Americans, or roughly 60 percent, show signs of cataracts today. Of this number, over 1 million will seek cataract surgery (at a total cost of over $3.5 billion) in 1985 to correct this disabling and potentially blinding disorder. Fortunately, this operation is almost always dramatically successful.

The word cataract is derived from a latin word meaning "waterfall." In fact seeing through a cataract can be like trying to look through a waterfall. Cataracts are cloudy or opaque areas in part or all of the tranparent lens located inside the eye. They develop gradually and painlessly until, in some cases, light cannot pass through the lens and vision is seriously affected. Cataracts are the current leading cause of blindness in the United States today.

Treatment of cataracts involves the surgical removal of the cloudy lens and the replacement of the natural lens with either eyeglasses, contact lenses, or an intraocular lens (IOL) implant, all of which are referred to as "prosthetic" lenses. Each has advantages and disadvantages.

Eyeglasses have been used for decades to restore vision following cataract surgery and their value is unquestioned. However, they are extremely thick, heavy and limit peripheral vision. Compared with cataract eyeglasses, contact lenses provide a much more natural means of visual correction following surgery — peripheral vision is practically normal. The main disadvantages of contact lenses are that many elderly patients do not possess the manual dexterity necessary to handle them and the eye may not tolerate the contact lens or contact lens solutions. Intraocular lenses, or IOLs, developed in 1949, have the advantage of one-time insertion at the time of surgery, and require no attention from the patient in the future. Another advantage is the presence of immediately useful vision that continues at all times, under all conditions of work, weather, and general health.

IOLs have become the lens replacement of choice following cataract surgery. The percentage of cataract patients having IOLs implaned during surgery has increased from 35 % of operations in 1980 to the current level of about 65 %.

Today, in large part due to increased demand and improved technology, cataract surgery and IOL implantation have become big business. In 1983, the most frequently reimbursed major surgical procedure under the Medicare program was cataract surgery. The government, under the Medicare program, pays the lion's share of the $3.5 billion associated with cataract surgery, about 80 %. The rest comes out of the pockets of the seniors themselves.

What follows is a summary of the Subcommittee's investigation into cataract surgery in the United States. It is an attempt to determine whether Medicare's dollars are wisely spent, whether the taxpayer's dollars are wisely spent, and whether our nation's older Americans are receiving the most appropriate care available.

I. BACKGROUND

A. Cataracts: A Definition

If one lives long enough, one will probably get a cataract. Today, one million older Americans, or roughly about 60 percent of people between the ages of 65 and 74 show some signs of cataract, and about 3.3 million people in the United States are visually impaired by this disorder. At least 42,000 people are blind from cataracts, making it the second leading cause of legal blindness in the United States; about 4,700 new cases of blindness from cataracts occur each year. In sum, a person living a normal life span is more likely to undergo a cataract operation than any other major surgical procedure, and no other operation is as frequently dramatically successful.

The word cataract is derived from the Latin word "cataracta", which means waterfall. In fact, seeing through a cataract can be like trying to look through a waterfall.

Cataracts are cloudy or opaque areas in part or all of the transparent lens located inside the eye. Normally, the lens is clear and allows light to pass through. When a cataract forms, light cannot easily pass through the lens and this affects vision. See Figure I below.

Figure I

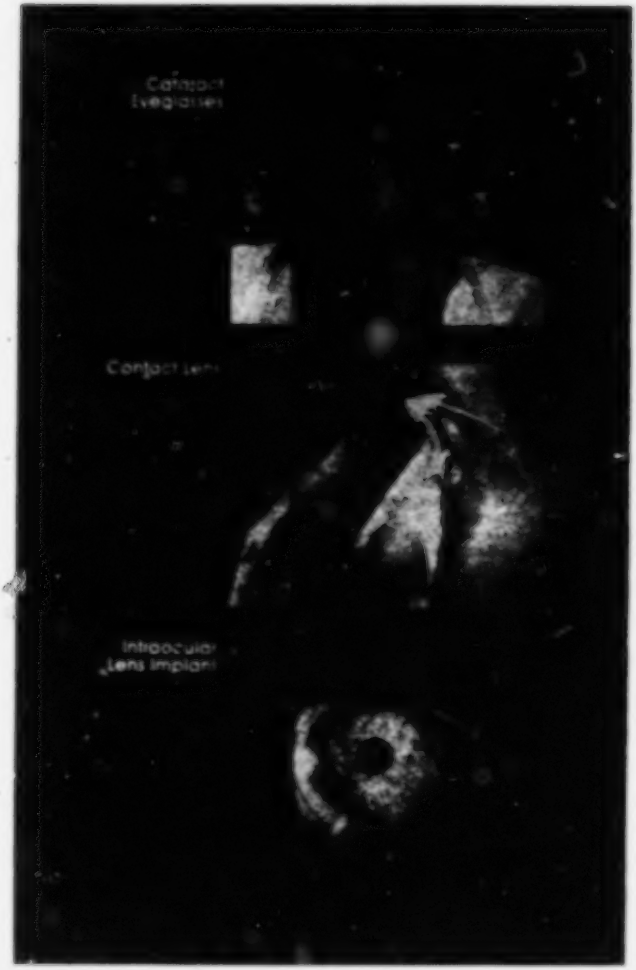
Cataracts usually develop gradually, without pain, redness, or tearing in the eye. Some remain small and do not seriously affect vision. If a cataract becomes larger or denser, however, it must be surgically removed to restore sight. Cataract surgery is a procedure in which the cloudy lens is removed. It is a safe procedure that is almost always successful.

What causes a cataract? When a cataract forms, there is a change in the chemical composition of the lens. It is not known what causes these changes. Cataracts have been associated with a number of different conditions, including aging, and eye injuries. What is not known, in most cases, is how and why these conditions cause the lens of the eye to cloud up.

What are the different kinds of cataracts? According to the National Eye Institute, the most common forms of cataract are as follows: senile cataracts are related to aging, although this type can occur at or before age 50. Congenital cataracts are present at birth or develop within a year after birth. Traumatic cataracts are those resulting from an eye injury or exposure to harmful chemicals. Drug-induced cataracts are those induced by the toxic effects of certain drugs that are given as medication, chiefly cortisone and its derivatives. Radiation cataracts are associated with radiation (such as X-rays and microwaves), intense heat or intense light (ultraviolet light or sunlight). Secondary cataracts are those that are complications of eye or general disorders. People who have glaucoma, iritis, uveitis, or ocular tumors may develop cataracts. Diabetes and other metabolic disorders can also lead to cataract formation.

Signs that cataracts are forming include hazy, fuzzy, or blurred vision; the appearance of dark spots in the field of vision; the need for frequent changes in eyeglass prescriptions; a feeling of having a film over the eyes; changes in the color of the pupil, which is usually black; and problems with light, for example, night driving. Of course, none of these signs separately or together necessarily means that a person has a cataract.

Figure II[1]



1. Cataracts, U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, Washington, D.C., NIH Publication No. 83-201, September, 1983, page 12.

B. Treatment of Cataracts: Methods, Progress, and Developments

Treating cataracts involves two steps. The first is surgical removal of the clouded lens by an ophthalmologist. According to the National Eye Institute, this is the only method proven effective for treating cataracts. The second step is finding the appropriate substitute for this natural lens.

Basically, there are two surgical methods for removing the clouded lens: intracapsular and extracapsular extraction. These methods are described later in this report.

When the cloudy lens, or cataract, is surgically removed from an eye, the resultant state is termed "aphakia." The aphakic eye lacks the optical power to bring visual objects rays to focus on the retina, permitting those objects to be seen.

There are three options for replacing the natural lens removed in cataract surgery: eyeglasses, contact lenses, or an intraocular lens implant, all of which are otherwise referred to as "prosthetic lenses." (See Figure II on the following page.) Each has advantages and drawbacks.

1. Eyeglasses

Eyeglasses have been used for decades for the correction of aphakia, and their value is unquestioned. They provide sharp central visual acuity and still serve as the visual standard against which other methods of correction are judged. However, they do have certain disadvantages; they are heavy, thick, and magnify all objects viewed. Other unpleasant effects can include poor side vision, poor depth perception, headaches, dizziness, and nausea.

The effect of image magnification is perhaps the most disconcerting attribute of spectacle cataract correction, for it makes it impossible to wear a cataract glass for one eye and routine corrective lens over the other. This occurs because the magnification of the aphakic image in comparison to the image from the nonoperated eye are different sizes, producing intolerable blur and double vision. Many patients find this effect hard to understand before cataract operation, and thus are particularly surprised and unhappy to learn that they must use one eye or the other after the operation, but not both. Since many patients have advancing cataract in one eye with very few changes in the other, there may be years between operations on the two eyes, creating a long interval of visual disability. Such patients will probably be advised to use a contact lens, or to have a lens implant as part of the operation to remove the cataract.

Only a minority of cataract patients today are prescribed cataract eyeglasses following cataract surgery given the advantages of alternative prosthetic lenses.

2. Contact Lenses

Compared with spectacle lenses, contact lenses provide a much more natural means of visual rehabilitation following cataract surgery. Objects are still magnified — much less so — and peripheral vision is practically normal. Also, contact lenses are quite safe if handled and maintained properly, and are especially helpful after cataract extraction in one eye. The main disadvantages of contact lenses are that many elderly do not possess the steady hands necesseary to handle them and the eye may become allergic to the lens or to the contact lens solutions. Finally, one age-related change in the human eye is decreased production of one or more components of tears, and good tear production is essential for the use of contact lenses.

Recently, high water content contact lenses have become available, which can remain in the patient's eye for extended periods of time. These lenses are more convenient for elderly patients, but are associated with an increased incidence of corneal infections and thickening of the cornea. Often a family member must be instructed regarding the removal and care of the contact lens should an emergency arise in which the patient is unable to manage.

Wearing contact lenses requires periodic ophthalmic follow-up and most types of soft contact lenses must be replaced yearly. It is estimated that over a period of 20 years contact lenses are approximately three times as expensive as intraocular lenses for the correction of aphakia.

For near tasks, like sewing or reading, regular eyeglasses (not cataract spectacles) are required in addition to contact lens.

3. Intraocular Lenses (IOLs)

The third form of aphakic correction is the intraocular lens implant. This has the advantage of one-time insertion at the time of surgery, with no attention required from the patient in the future. Another advantage is the presence of immediately useful vision that continues at all times, under all conditions of work, weather, and general health.

These lenses are usually fabricated of rigid plastic, although the mechanical appendages that stabilize the lenses in the eye can be of other synthetic materials, such as Prolene or nylon. The general shape of these lenses, their location in the eye, the type of operation required for their insertion, and frequency of use will be discussed later in this report. Conventional eyeglasses (not cataract spectacles) often are required in addition to intraocular lens implants.

Because of the many advantages, lens implants have been used with increasing frequency in recent years. There has been a steady increase in the number of cataract operations, fueled, in part, by the increasing number of elderly. The percentage of cataract patients having IOLs implanted has increased sharply from 32% in 1980 to the current level of about 85%. This growth has accelerated in the last few years, probably as a result of the acceptance of IOLs and a growing patient awareness that it is no longer necessary to have the extremely thick, uncomfortable and limiting glasses which previously were prescribed for cataract patients. In addition, cataract removal has become a much simpler surgical procedure with new techniques and better surgical instruments, which will be discussed later in this report. A history of the development of intraocular lenses follows.

Historical Development of IOLs

Harold Ridley, a British ophthalmologist, carried out the first IOL implant operation on November 29, 1949. Observing that fragments of plexiglass from shattered cockpit canopies could be tolerated within the eyes of British airmen, he began the era of IOL implantation by designing a lens that could be inserted into the posterior chamber between the iris and remaining posterior capsule. (See Section IX on the anatomy of the eye) His first patient, a 45-year-old woman, had a severe residual myopia. She tolerated the lens relatively well. He was thus encouraged to perform his second implantation on the 23rd of August, 1950. Ridley inserted approximately 1,000 of his original IOLs. Many of his cases remained successful as late as 1966. By 1970, however, Ridley reported that removal of his implants was necessary in at least 15% of cases.

A major reason for Ridley's limited success was that the surgical techniques and instrumentation available in 1949 were not comparable to today's technology, not the least of which are the operating microscope and neodymium-YAG laser. For example, the operating microscope allows much greater access and visualization of the tiny, delicate portions of the eye.

The difficulties associated with Ridley's posterior chamber IOL led to experimentation with anterior chamber IOLs. In 1952, Baron was the first to implant an anterior chamber lens.

In June 1953, following the continued development of anterior chamber IOLs, Epstein introduced the "collarstud" lens, which was an iris supported lens. The original iris-clip lens was introduced by Binkhorst in 1957 and used for the first time in 1958. The iris-fixated lenses attempted to overcome complications of posterior chamber lenses, namely lens dislocation, and the most important complication arising from anterior chamber lenses, namely lens corneal touch and corneal damage.

Many of the iris-supported lenses were very successful and did much to popularize the concept of intraocular lens implantation throughout the world. Indeed, many patients who have had excellent long-term visual rehabilitaiton with IOLs of this type survive today. However, there are others who have experienced complications with these IOL styles. This has led to an eventual abandonment of these styles in favor of well-designed modern anterior and posterior chamber lenses. From February 1978 to August 1982, the rate of iris-fixated lenses implanted (expressed as a percentage of total IOLs implanted) declined from 52% to 6% of lenses implanted.

From 1975 to the present, information from the extensive clinical experience with IOLs during the past decades has contributed to a rapid and highly innovative era of IOL development. Of utmost importance has been the increasing use of posterior chamber implantation. Numerous modern, well-designed anterior and posterior chamber IOLs have been introduced. There has been continuous improvement in lens design and in IOL manufacturing techniques. Implantation techniques are far more refined and are safer.

In some instances, the frequent introduction of new IOL designs (Table I is only a partial listing of IOL models available to surgeons) actually creates a problem. It is sometimes difficult for the implant surgeon to decide which IOL is the best in his or her view and for each individual patient.

Although a few iris-supported lenses continue to be implanted, they have largely become obsolete. The overall rate of success achievable with these lenses cannot compare to the results obtained by experienced surgeons with modern posterior and anterior chamber IOLs.

The most important breakthrough was a return to Ridley's original idea of the posterior chamber IOL. This is now possible because of : 1) the development of new lens designs which are lighter in weight and provide better fixation, and 2) the introduction of improved surgical instrumentation and techniques. Table I, which follows, displays the evolution of intraocular lenses.

Table I

*Evolution of Intraocular Lenses**

Generation I — (ca 1949-54)† — Original Ridley Posterior Chamber Lens
1. Ridley, 1949
2. Parrs (implantation modification, 1954)

Generation II — (ca 1952-1962) — Development of Anterior Chamber Lenses
1. Rigid or semi-rigid
   - Baron, 1952, 1954
   - Scharf, 1953
   - Strampelli tripod, 1953
   - Schreck, 1954
   - Binetti, 1955
   - Choyce Mark I, 1956
   - Ridley Mark I and II, 1957, 1960
   - Boberg-Ans, 1961
2. Flexible or semi-flexible loops
   a. Closed loops
      - Dannheim, 1952
      - Strampelli, 1956
      - Lieb and Guerry, 1957
   b. Open loops
      - Barraquer, J-loop, 1959

Generation III — (ca 1953-1970) — Continued Development of Anterior Chamber Lenses and Introduction of Iris-supported Lenses
Anterior Chamber
1. Rigid or semi-rigid
   - Choyce Mark II, 1957 to Choyce Mark VIII, 1965
2. Flexible

Iris supported
- Epstein "collarstud" lens, 1953
- Binkhorst iris clip, 1957, 1958
- Epstein Maltese cross (evolved into the Copeland-Binkhorst lens), 1962
- Fyodorov Type I iris clip, 1964
- Binkhorst iridocapsular, 1965
- Fyodorov V-type II, Sputnik iris clip, 1968
- Worst Medallion iridocapsular, early 1970s
- Worst Platina, early 1970s

Generation IV‡— (ca 1975 to present) — Major Improvements in Microsurgical Techniques, Lens Design and Lens Materials; Introduction of Posterior Chamber Lenses*

Anterior Chamber Lenses
1. Rigid or semi-rigid
   - Azar Mark II, 1977
   - Tennant Anchor, 1979
2. Flexible or semi-flexible loops or footplates
   a. Closed loops
      - Leiske, 1978
      - Hessburg, 1981
      - Optiflex, 1981
      - Azar 91Z, 1982
      - Stableflex, 1983
   b. Open loops or footplates
      - Kelman II, 3-point fixation, 1978
      - Kelman Quadriflex, 1981
      - Kelman Omnifit, 1981
      - Kelman Multiflex, 1982
   c. Radial loops
      - Copeland, 1982

Posterior Chamber Lenses
- Pearce rigid tripod, 1975
- Shearing J-loop and its late 1970s, early 1980s

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Table I (cont.)

Simcoe C-loop, mid to late 1970s, early 1980s
Simkey, modified J-loop, mid to late 1970s, early 1980s
Kratz, modified J-loop, mid to late 1970s, early 1980s
Clayman, modified J-loop, mid to late 1970s, early 1980s
Lindstrom, modified J-loop, mid to late 1970s, early 1980s
Harris, I open, I closed loop, modified J-loop
Closed modified J-loop both loops closed (e.g., Sheets, Galand, Knolle)
Osher-Fenzl, modified J loop with loophole at tip of superior loop
Lewicky, modified J-loop with loopholes at tips of both loops
Ridged lenses for YAG laser capsulotomy, e.g., Hoffer ridge
IOLs with UVR absorbers in optics
IOLs with biconvex or aspherical optics
Lynell, glass optic
Mazzocco silicone (elastic) IOL
"Universal" types (designed to be placed in either anterior or posterior chamber" (early 1980s)
Shepard Universal (radial loops)
Feaster Dualens
Pannu type III

*Partial listing of representative lenses.

†Some dates are estimates since manufacturers' data are not always available. We have attempted to document the date of the surgeon's initial implantation rather than the date of his published reports or year of marketing of the lens.

2. "Complications of Intraocular Lenses. A Historical and Histopathological Review," Survey of Ophthalmology, Volume 29, Number 1, July-August, 1984.

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C. IOL Implantation Procedure

Implantation of the intraocular lens (IOL) follows the removal of the patient's clouded lens (cataract) by the ophthalmologist. The procedure may be performed on an inpatient or outpatient basis, and local or general anesthesia can be used. The procedure can take anywhere from 20 minutes to two hours to perform, depending on methods used and operating conditions. Routine cataract extractions should take no more than 40 minutes and some physicians can perform this operation in 12 to 20 minutes. For the patient, the procedure can mean three hours in an outpatient facility or up to three days in the hospital.

Two different surgical procedures are commonly used for removal of cataracts and insertion of IOLs: extracapsular and intracapsular extraction. The extracapsular procedure has increased in use since 1981, displacing intracapsular extraction as the more common procedure. (See Table II below) According to Table II, between 1981 and 1983, extracapsular extraction increased from 29.4% to 51.9% of all surgical cataract procedures, while intracapsular extraction fell from 68.1% to 43.8%.

Table II

Shift in Type of Surgical Procedure
Used to Extract Cataract

	Extracapsular Procedure	Intracapsular Procedure	Other Procedures
1981*	29.4%	68.1%	2.5%
1982	39.3%	57.0%	3.7%
1983	51.9%	43.8%	4.3%

*1981 NEDPAR data indicate that 31.9 percent of cataract extractions were intracapsular and 70.2 percent were extracapsular

Source: Hospital Discharge Survey, National Center for Health Statistics. For cataract extractions in patients 65 and over

The extracapsular procedure tends to take longer, but both procedures including lens implantation should still require less than an hour of operating time Both procedures begin with a 5 to 7mm incision in the eye.. Frequently, sodium hyaluronate (Healon), or a similar viscoelastic material, is used to maintain the shape of the eye and protect the cornea and other delicate structures during surgery.

Intracapsular extraction is commonly used to remove cataracts associated with aging, and is rarely used in patients under 30 years of age. In this method the entire lens and its capsule are removed. One popular technique uses an enzyme, alpha chymotrypsin, to weaken the ligaments which hold the lens in place. Then a very cold probe is inserted and used to freeze a portion of the lens. The frozen part of the lens sticks to the probe and allows the surgeon to lift the lens out of the eye easily. This technique is called cryoextraction.

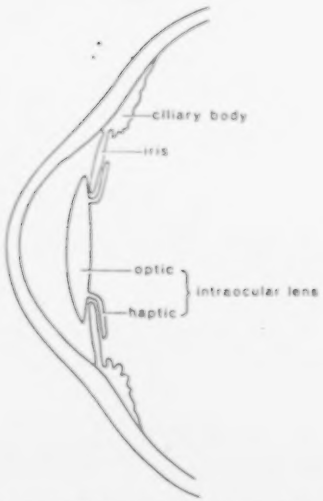
Extracapsular extraction leaves the back portion of the lens capsule intact, while most of the lens and the front part of the capsule are removed. The aspiration method is used to remove congenital and other cataracts in infants and young children, whose lenses are relatively soft. The lens capsule is opened and the soft lens is suctioned out (aspirated) through a hollow needle. For adult patients with harder lenses, the surgeon may employ phacoemulsification, a technique whereby high frequency sound vibrations are used to soften and liquify the lens, enabling the lens to be aspirated through the hollow needle.

After the lens is removed, one of three different types of IOLs can be implanted: the iris supported lens, the anterior chamber lens, and the posterior chamber lens. Iris supported lenses (see Figure III on the following page), anchored by loops to the iris, were the first to be used extensively. These lenses may move about when the eye moves causing corneal damage. Few iris supported lenses are implanted today.

Anterior chamber lenses (see Figure IV), placed in the angle between the iris and cornea, must be accurately sized. They are easy to install and remove, making them very popular.

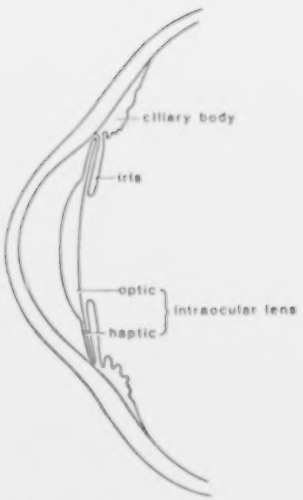
Recently, the combination of an extracapsular cataract extraction with the implantation of a third type of lens, the posterior chamber lens (See Figure V) has become the most popular procedure in the United States. Extracapsular extraction is advantageous for two reasons. First, the remaining portion of the capsule tends to hold the vitreous humor, a viscous fluid found in the eye, in its normal anatomical position in the back of the eye. Second, the capsule itself serves as a support for the posterior chamber IOL, which in this case rests behind the pupil in the natural position of the patient's own lens.

Figure III



Iris supported lens. This lens depends solely on the constricted iris for its support in the eye. In some cases, a suture is passed through a hole in the superior part of the optic securing the lens to the iris. This in turn allows partial diagnostic dilation without lens dislocation.

Figure IV



Anterior chamber intraocular lens. Note that the lens is supported by the tissue in the angle where cornea and iris meet.

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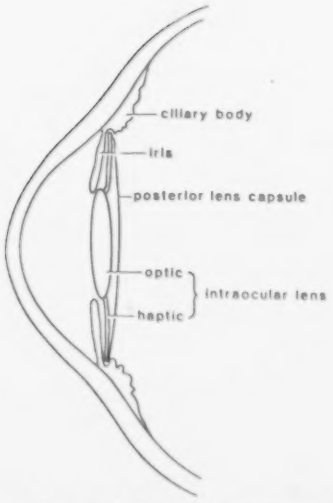
Figure V



Posterior chamber intraocular lens. This implant rests primarily on the posterior lens capsule left behind when the extracapsular cataract extraction is performed.

With the extracapsular extraction-posterior chamber IOL there is a tendency for the capsule to become somewhat opacified several months after the operation. This complication, occurring in 40-50% of patients, necessitates an incision of the capsular membrane with a surgical knife or a non-heat producing Nd:YAG (neodymium-yitrium garnet) laser. The laser treatment is essentially non-invasive and atraumatic for the remainder of the structures in the patient's eye.

Even with the possibility of subsequent membrane formation (clouding), many ophthalmic surgeons are convinced that the posterior chamber lens implant is superior to those described above and it seems likely that the majority of lens implantations done in the United States over the next several years will be of this type. While only 4% of IOLs implanted in 1978 were posterior chamber lenses, today about 60% of implantations involve the use of these lens. (See Table III below).

Table III

Percent of Intraocular Lenses Implanted By Type of Lens For Each Six Month Period

	1978	1979		1980		1981		1982		1983		1984
Type Of Lens	Aug	Feb	Aug	Feb	Aug	Feb	Aug	Feb	Aug	Feb	Aug	Feb
Anterior Chamber ...	25%	25%	32%	31%	32%	32%	35%	37%	41%	36%	32%	30%
Posterior Chamber ..	4%	8%	13%	21%	30%	37%	43%	47%	50%	58%	65%	69%
Indocapsular	19%	17%	13%	10%	8%	7%	4%	3%	2%	1%	<1%	<1%
Iris Fixation	52%	50%	42%	38%	30%	24%	18%	13%	7%	5%	3%	<1%

Source: Shin, Walter, et al. Update of Intraocular Lenses Implanted in the United States. Ophthalmology. 88:236-239. 1984

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D. IOL Industry: U.S. and Abroad

The manufacturing and distribution of IOLs is a fast growing, highly competitive and highly profitable industry in this country. In 1985, the IOL industry will sell $325 million worth of its lenses. Most were implanted in the eyes of elderly patients following cataract surgery. Fueled by the increasing number of elderly, the growing acceptance of IOL implants, and unbridled Medicare payments for IOLs, estimates are that IOL sales will hit $700 million by 1990 when well over one million IOL implants will be performed in the U.S. each year.

The percentage of cataract patients having IOLs implanted has increased sharply, from 32% in 1980 to the current level of 85%. This has resulted in rapid growth for the entire industry. Today no fewer than 30 companies worldwide are in the business of making IOLs, putting out at least 400 different models. The field is dominated by five large medical companies which entered the market by acquiring much smaller firms in the late 1970s, and together they control over 70% of the market. The leaders, by sales volume, are Johnson & Johnson's IOLAB, Rorer Group's CILCO, Intermedics, Optical Radiation Corporation, American Medical Supply's American Medical Optics, and Frigitronics' Precision Cosmet. (See Table IV)

Table IV — Major IOL Manufacturers

Allergan/ISP, 2525 Dupont Drive, Irvine, California 92713.
American Medical Optics, 1402 East Alton Avenue, Irvine, California 92714.
Americal IOL International, 15542 Graham Street, Huntington Beach, California 92647.
CILCO, Inc., 1616 13th Avenue, Huntington, West Virginia 25701.
Coburn Optical, 1375 South Ft. Harrison, Clearwater, Florida 33517.
CooperVision, Inc., IOL Division, 3190 160th S.E., Bellevue, Washington 98008.
Copeland Intra Lenses, Inc., 129 East 61st Street, New York, New York 10021.
Eye Care Corporation, Suite 100, 201 Summit View Drive, Brentwood, Tennessee 37027
Intermedics Intraocular, Inc., 169 North Halstead Avenue, Pasadena, California 91107
IOLAB Corporation, 861 South Village Oaks Drive, Covina, California 91724.
Ioptex Inc., 1301 Optical Drive, Azusa, California 91702.
Optical Radiation Corporation, 1300 Optical Drive, Azusa, California 91702.
Pharmacia Ophthalmics, 800 Centennial Avenue, Piscataway, New Jersey 08854.
Precision Cosmet, 11140 Bren Road West, Minnetonka, Minnesota 55416.
Surgidev Corporation, 5775 Wayzato Boulevard #855, Minneapolis, Minnesota 55146.
Staar Surgical, 1911 Walker Avenue, Monrovia, California 91016.
Storz Instrument Company, 3365 Tree Court Industrial Boulevard, St. Louis, Missouri 63122.
3M Vision Care IOL, 340 Storke Road, P.O. Box 2360, Goleta, California 93118-2360.

Positions can shift quickly in this immensely profitable and competitive industry due to innovation and marketing. The unique way in which the FDA regulates this market facilitates market entry and expands the ranks of competitors. This will be discussed in greater detail later in this report. For example, Optical Radiation entered the market four years ago with the first IOL with a UV light blocking additive, and now owns at least 13% of the market. For its part, the FDA has been slow to grant full approval to market IOLs, while it allows distribution to qualified surgeons on an almost unlimited basis prior to approval. In order to use the lens the surgeon is required to complete paperwork which makes him part of the investigative process. There are now over 900 IOL models being marketed, but only 76 have received full FDA approval. The first approval came in 1981, by which time there were over 500,000 lenses implanted.

To stay ahead of their competitors, the major companies spend on average 10% of their revenues for research and development of new lenses. They spend enormous sums of their money on marketing and have even engaged in price cutting to gain additional market share.

Comparing the industry in the U.S. and abroad, the main difference seen is in the costs to consumers for lenses. The costs in Europe are roughly half of what they are in the U.S. while the cost to the manufacturer per lens ($35-$50) is roughly the same.

The outlook for the industry in the U.S. is positive for the next few years as the population ages and the increase in the number of cataract operations continues. It is

suspected however that the recent sharp increase in cataract operations are using up a pool of those who were postponing the operation as long as possible, but went ahead when they were satisfied with the success of IOLs. The total number of operations should level off sometime in the mid-1990s, when the capacity to perform these operations catches up with the population requiring them.

E. Cataract Surgery: Numbers and Costs

Cataract surgery is a large and ever growing industry in this nation. This year Americans will spend over $3.5 billion for the removal of over 1.1 million cataracts and the implantation of over 1 million IOLs. The rate of cataract surgery has more than doubled since 1980 and it is projected to double again by the end of this decade. In 1980, there were 415,000 cataract operations. In 1989, over 2 million such surgeries are expected to be performed. (See Table V)

Table V

U.S. Cataract Procedures
(1984-1989)

	1984(a)	1985(b)	1986(b)	1987(b)	1988(b)	1989(b)
Total Cataract Procedures	989,207	1,187,000	1,424,000	1,709,000	2,051,000	2,200,000
IOL Implants(c)	840,650	1,020,820	1,238,880	1,486,830	1,784,370	1,914,000

(a) 1984 figures based on actual FDA data.
(b) Projected.
(c) Included in Total Cataract Procedures above.

Other relevant facts relating to cataract surgery include:

- $3.03 billion was paid by the Medicare program alone -- the rest came out of seniors themselves.
- Most cataract patients and IOL recipients are elderly. Roughly 900,000 of the over one million IOL implantations to be performed this year will involve older Americans.
- Since the late 1970s, IOL sales have increased from virtually nothing to well over $300 million. Those knowledgeable in the IOL industry estimate that the actual cost of manufacturing a standard quality IOL should range from $35-$50.
- The price of an IOL through competitive bidding in the hospital is sometimes less than $100 in 1985. The price of an IOL to the Medicare program out of hospital is $300 to $750 in 1985.
- The Subcommittee indicates the final cost to the purchaser of cataract surgery (whether that is the Medicare program or private consumers or some combination thereof) ranges from around $300 to $750 and over.

F. Medicare Payment for Cataract Surgery and IOLs

The lion's share of monies paid for cataract surgery come from the pockets of the American taxpayer. The Federal government through the Medicare program pays upwards of 85 percent of this nation's annual bill for cataract surgery ($3.03 billion out of a total of $3.56 billion this year).

The Medicare program, which is authorized under title XVIII of the Social Security Act, consists of two separate but complementary types of health insurance for the aged and certain disabled persons. Part A, the hospital insurance program, provides protection against hospital and related institutional costs. Part B, the supplementary medical insurance program, covers physicians' services and a number of other medical services.

Under Part A, the Health Care Financing Administration reimburses hospitals for inpatient care on a prospective basis, subject to specified deductible and coinsurance amounts. All inpatient treatments and surgical procedures have been classified and assigned to one of 467 different diagnostic related groupings (DRGs). This approach to health care reimbursement operates on the principle that patients with similar medical conditions should receive similar care and should use approximately the same amount of resources; therefore, in general, a hospital should be reimbursed the same amount for each patient in a DRG. The inpatient deductible in 1985 is $400.

Part A generally does not cover physician services rendered to hospital inpatients; payment for such services is made under part B. Part B pays 80% of a patient's doctor bills and 80% of bills for outpatient services, after the patient exceeds his or her one-year deductible. The patient deductible in 1985 is $75.

For cataract surgery and IOL implants, serious concerns have arisen over the very different amounts of reimbursements and beneficiary contributions which Medicare creates -- depending on where and how the identical surgery and procedures are performed, be it in the hospital as an inpatient or outpatient, in an ambulatory surgical center (ASC) or freestanding surgical clinic, or in a physician's office. The surgeon performing the operation receives from Medicare roughly the same fee of $1200 regardless of where the cataract surgery is performed. The discrepancies arise when one looks at the costs for facility fees and lenses at the different locations, which will be discussed in detail in Section II B of this report.

II. CURRENT PROBLEMS

A. Efficacy and Safety

Recent improvements in IOL design, manufacturing and surgical techniques have greatly reduced the incidence of complications following implantation, and many authors now consider IOL implantation one of the most safe and effective major surgical procedures. However, adverse reactions are still seen -- some as late complications of earlier IOL designs and implantation techniques, and some as the result of more recent implantations using "state of the art" lenses and surgical techniques. Complications may be due to various factors including surgical technique, IOL design, or the inability of some eyes with preexisting diseases to tolerate an implant.

Ophthalmic surgeons generally feel that 95% of cataract patients achieve what might be termed "technical success." This refers to a lack of significant complications related to the removal of the opaque lens, but does not allow for underlying, unexpected abnormalities of the retina or optic nerve, which can seriously interfere with final visual capability. When intraocular lens implants are used, additional complications can occur as a result of the lens implant itself. For example, the basic cataract operation is made somewhat more difficult technically by implant placement, so that there is a slightly greater likelihood of damage to the cornea, iris, or vitreous body. More important are those complications, such as lens dislocations and chronic inflammation, that are specifically due to the plastic implant. These complications may occur in an additional 2 to 3% of cataract patients, and of course are added to those complications of the usual cataract operation. Most patients are willing to commit themselves to this slightly higher risk of complications to achieve the benefits of the intraocular lens implant.

As part of the healing process which occurs following removal of a cataract and insertion of an intraocular lens, portions of the implant which are in direct contact with soft tissues inside the eye usually become imbedded within those tissues. In the vast majority of cases implants are well tolerated and this "healing-in" process actually stabilizes the implant. On rare occasions, however, the implant may cause a low-grade, chronic inflammation within the eye. Many surgeons now feel that if the supporting elements of the posterior chamber lens are inserted within the relatively inert capsular bag, this potential problem can be avoided altogether.

In the past, insertion of poorly manufactured intraocular lenses produced inflammatory reactions, intraocular bleeding, and reduced visual acuity. Strict quality control measures during the past few years have largely eliminated these problems.

Only rarely does an IOL implant require subsequent removal. The usual indication for this is persistent inflammation. Persistent glaucoma, or advancing corneal degeneration as a result of the implant may also be indications for lens removal. Persistent inflammation may be coupled with persistent swelling of the macula of the retina (cystoid macular edema), may lead to a significant reduction in visual acuity. Whether or not the removal of the implant is useful in reversing this complication is not entirely clear, but most surgeons feel that it is prudent to remove the implant if the retinal edema persists for more than a few months.

One IOL which deserves special mention is the ultra violet (UV) lens, an IOL with an additive which filters out UV light before the light reaches the retina. Many surgeons say they buy UV lenses because their patients ask for them, not because they believe in them. Despite the publicity and claims made for UV lenses, there is no medical evidence that ultraviolet light damages the retina. There is also no information on the long-term effects of the UV filtering additive used in these lenses. Ultraviolet light can also be blocked by glasses and, until further data is in, some experts believe glasses may be preferable to the UV IOLs.

Because current types of IOLs have been in use for little more than a decade, there has not been time to learn how these devices might affect the eye over a period of many years. However, results to date have been very encouraging. In the three decades since the introduction of IOLs by Ridley, successful tolerance has been measured over postoperative periods of 5-10 years. However, by today's implantation criteria, in which lenses are being implanted in younger and younger patients (who, by actuarial statistics, are going to be living longer and longer), IOLs should now be expected to be safe and stable within the eye for periods of 10-30 years. Therefore we have now reached an era where one of the most important considerations in IOL implantation is the need for very careful long-term follow up of patients. This is necessary for the surgeon to obtain highly successful visual rehabilitation over the long term. To obtain additional information that will aid cataract patients and their doctors in making decisions about about the use of IOLs, the National Eye Institute is supporting research on these devices and their long-term safety.

B. Cost: IOLs and Medicare Reimbursement Practices

Medicare payments for cataract surgery with IOL implantation are made under a system which pays grossly different sums for identical surgical procedures, depending on where those procedures are performed. This system, designed to improve efficiency and save money, is doing just the opposite, and without regard to patient well-being.

The following elements are incorporated into the total IOL implantation cost borne by the Medicare program and, ultimately, the American taxpayer:

- manufacturing and marketing costs for IOLs;
- parts (disposable liquids, knives, tools, etc.);
- viscoelastic materials and operation-associated equipment;
- hospital or facility markup;
- hospitalization (inpatients only);
- operating room and related costs;
- professional fees, including the referring physician, surgeon (and assistant surgeon in some cases), and anesthesiologist (if used); and
- followup.

When the IOL implantation is performed in the hospital on an inpatient basis, the the hospital is reimbursed by the prospective payment system of Medicare part A, under DRG 39. When the same procedure is moved to the outpatient setting in the same hospital, outside of the DRG domain, that same hospital can now bill Medicare, under part B, its "reasonable costs" almost four times as much as Medicare's inpatient cost, for for the identical procedure bundled with fewer services.

Our investigation indicates costs are excessive and profit is inordinate at two major levels: the price of the lens in hospital outpatient settings, and the facility fees paid to hospitals for outpatient cataract surgery and the lens implants. The cost of cataract surgery and lens implantation varies greatly on the basis of where the implantation takes place: in the hospital, hospital outpatient, ambulatory surgical center, or in the physicians' office. With regard to these cost elements, our findings are as follows:

1. IOL Costs

The manufacturer's IOL list price includes the cost of materials and manufacturing processes, general administration, marketing and sales, research and development, tax and profit.

The average IOL currently costs $35-$50 to manufacture and is sold to hospitals and surgical centers in the United States for an average of $321. (See Table VI). In practice, the principal difference between product cost and sales price consists of marketing and profit.

Table VI

Average Price of Intraocular Lenses And Healon

Lens Type	1981	1982	1983	1984
Posterior Chamber	$277.50	$280.00	$291.14	$314.60
Anterior Chamber	--	$290.00	$317.35	$330.39
(IOL) Fixation	--	$257.00	$312.14	$308.31
Other	$258.50	$334.41	$450.01	$340.43
Healon	$ 53.35	$ 60.00	$ 62.50	$ 58.11
Weighted Average for IOLs	$258.77	$290.33	$305.17	$322.00
Weighted Average for IOLs And Healon	$283.43	$309.55	$345.05	$339.03

Source: IOL America and IOL Source Book

Given the essential equivalency of the lenses and Medicare's insensitivity to price, it is not surprising that marketing costs are significant. Almost 50 percent of the list price of an IOL is dedicated to marketing. Roughly two thirds of that total — 30 percent of the list price — was paid by some firms as a commission to its sales representatives. The remainder was divided between direct marketing, advertising, travel, clinical investigations, and more innovative sales inducements. Some companies bundle $75 surgical packs with their lenses, and others even offer $85,000 YAG lasers with volume purchases.

Although the percentages may vary, and specific arrangements with the firms sales representatives differ, the general pattern is consistent. IOLs tend to be immensely profitable to manufacture and market.

IOLs are more profitable in the U.S. than abroad. A recent report in Barron's asserts that the very same lenses that are sold in the U.S. for $300 are sold in Europe for $120 to $150. To defend this pricing difference, one manufacturer told us that 99% of IOLs in the United States are supplied to hospitals on a consignment basis, resulting in additional inventory and handling costs of up to $50 per lens. In addition, we were told, the FDA requires paperwork amounting to an additional $30 per lens. Thus the manufacturer accounted for roughly half the pricing difference. A securities firm which follows the IOL industry asserted that in Europe, the bulk of lens sales are comprised of generic (standard) lenses, while the product mix in the U.S. is weighted more heavily in favor of the more expensive, technologically advanced, though questionably superior, products. While the eyes and sight of the citizens of Europe are no less precious than those of our own citizens, their governments have refused to pay exorbitant amounts for premium IOLs, when their national health insurance can provide perfectly adequate quality lenses for much less money. This is something Medicare is supposed to do.

Further evidence of the profitability of IOLs is shown by the willingness of manufacturers to reduce prices when hospitals required them to make competitive bids in order to secure lens purchases. As shown in Table VII on the following page, one hospital was able to reduce its average cost per lens from $321 to $229 just by requiring manufacturers to submit bids. One manufacturer actually reduced its IOL price by 58 percent. On volume purchases, some models of lenses may be acquired for less than $100.

In all, the Subcommittee found IOLs offered for sale to providers from $90 to $385. Discounts were offered by most manufacturers, some only when asked. Requiring competitive bids, and making volume purchases, are the most assured ways for hospitals, surgical centers, and consortiums to get the best possible prices for IOLs.

Hospitals performing inpatient IOL implants have a direct incentive to keep their costs for IOLs down — they receive a flat fee of $1,200 for facility expenses, including the lens, under DRG 39. Any extra dollar they spend for an IOL eats into their already tight margins and could even put them into the red. For hospitals performing inpatient surgery, it is clearly in their own best interest to buy IOLs at competitive prices.

Unfortunately, Medicare Part B, which covers IOLs implanted in outpatient settings, provides no incentives for keeping IOL costs down. In fact, it does just the opposite, encouraging outpatient facilities and Ambulatory Surgical Centers to pay top dollar for their IOLs, and then pass the cost on to Medicare. Some hospitals even mark up the IOL by as much as 260 percent, as can be seen in Figure VI on the following page, detailing patient charges at a Colorado hospital.

At present, many hospitals and ASCs are charging Medicare what they feel are "reasonable" costs for IOLs. They are paying the lens manufacturers their full "reasonable" list prices and then, after adding a "reasonable" markup for themselves, pass the entire "reasonable" cost on to Medicare. Medicare B encourages this practice by reimbursing providers for IOLs on a reasonable charge basis.

The reasonable charge is defined as the lowest of:

- the actual charge;
- the customary charge for the IOL (that is, an amount high enough to cover the IOL charges 50 percent of the times the IOL was purchased); or
- the prevailing charge for the area (that is, an amount high enough to cover 75 percent of the customary charges of all IOLs implanted in the area).

Table VII

VENDOR	Before Bids: % of Business	Average Cost Per Lens	Number of Lens	1983 Annual Cost	After Bids: % of Business	Discount	Average Cost Per Lens	Number of Lens	Projected Annual Cost	Project Annual Savings
Company A	9.8%	$350	147	$ 51,260	3%	15%	$298	64	$ 19,072	$ 3,328
Company B	3.5%	$325	52	$ 16,900	13%	58%	$138	264	$ 36,432	$ 49,368
Company C	27.5%	$325	412	$133,900	21%	20%	$260	428	$111,280	$ 27,820
Company D	31.9%	$300	474	$143,675	12%	25%	$225	240	$ 54,000	$ 18,000
Company E	26.7%	$325	399	$129,675	48%	30%	$228	976	$222,528	$ 94,672
Company F	0.8%	$360	12	$ 4,320	3%	0	$360	68	$ 24,480	0
TOTALS	100%		1,496	$479,730	100%			2,040	$467,792	$193,188
COST PER LENS				$ 321					$ 229	

BASED ON USE OF 1,496 LENSES IN CALENDAR YEAR 1983

BASED ON ANNUALIZED USE OF 2,040 LENSES IN FISCAL YEAR 1984-85

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Figure VI

MEDICAL CENTER

PATIENT CHARGES

		Hospital Cost	Markup
Amoils cryo unit	$ 13.89		
Beaver blade #69	9.20		
Beaver blade #64, #67	3.45		
Concept cautery	13.25		
Drape, 1010	6.10		
Drape, 1060	14.66		
Drape, 1020	6.58		
Elbow pads	6.90		
Filters	4.90		
Instrument wipe	4.80		
Lens, Ioptex 304-01	661.20	. . . . . 290.00	228%
Lens, Ioptex UV 304-1	798.00	. . . . . 350.00	228%
Lens, ORC UV	763.80	. . . . . 369.00	207%
Lens, Cilco Multiflex	946.20	. . . . . 335.00	282%
Lens, Cilco SK 21	741.00	. . . . . 340.00	218%
Lens, Iolab Sinskey 103N	741.00	. . . . . 325.00	228%
Lens, Coburn Mod 93	798.00	. . . . . unavailable	
Microknife	10.42		
Microscope	12.99		
Phacoemulsifier	425.86		
Phaco I & A	233.43		
Patch, eye	.69		
Shield, eye	3.45		
Suture, 4-0 Silk	8.00		
Suture, 9-0, 10-0	33.04		
Suture, allother	21.52		
Ultrasharp blade	41.04		
Weck-cel sponges	5.50		
Wet-field Cautery	13.25		
Vitrectomy Unit	328.60		

DRUGS

Adrenalin	4.50
BSS 15 ml	10.67
Carbocaine 20cc	4.78
Healon	137.50
Marcaine .75%	4.85
Maxitrol Oint	10.34
Miocohol	29.97
Tetracaine	2.31
Wydase	8.10
BSS pl	47.00
Zolyse	30.55
BSS ++	129.50

Rather than standardizing what Medicare pays for IOLs, this system allows IOL costs to vary widely from state to state, as can be seen in Table VIII below, which was gathered by the Subcommittee staff and the General Accounting Office in telephone interviews and written correspondence.

Table VIII

STATE	RATE(year)	RATE METHOD	Comments
Illinois	$375 ('83)	lesser of invoice or $375 for all	invoices not required; with claims; few submit with claims
Michigan	$450 or $600('85)	set prevailing rates/ pay lesser of customary or prevailing	2 geo areas w/
New York	$295-$360('85)	4 set rates for 4 lense types based on 75th percentile of previous year charges	asked to submit invoice/ few do
Mass	$665('85)	pay lesser of $665 or invoice	invoices not required; few submit
Arizona	$400('85)	pay lesser of $400 or invoice	
Wisconsin	$290('84)	$240 flat	
California	$350('85)		

One lens manufacturer contracted with the largest accounting firm in the health care industry, to determine the shipping and handling costs for IOLs on a per lens basis. That study came up with a figure of $55.15 per lens, much less than the 50 to almost 300% markups many providers have been passing on to Medicare for IOLs.

If the Medicare payment system for IOLs were revised to encourage providers to shop around for the best lens prices available, and then to reimburse the provider for that sum plus a genuinely reasonable handling charge, savings from 50-75 percent of the price of each lens could be realized. This translates in to annual savings of over $160 million.

When compared to the total amount of federal dollars wasted paying excessive fees for IOL implantation, the total made in overpayments for the IOLs themselves becomes trivial. The current Medicare payment system has encouraged abusive practices, and as shall be shown, is responsible for more than $1.2 billion per year in overpayments for outpatient cataract surgery. (See Table IX on the following page.)

2. Inpatient Hospital

Under the prospective payment plan of Medicare part A,cataract surgery has been assigned to DRG 39. Another classification, DRG 42, is used in a minority of cases. Under DRG 39, hospitals receive from Medicare roughly $1200 (plus or minus $300 for regional differences) for facility fees incurred during cataract surgery. The hospital receives the same fee whether an IOL is implanted or not.

According to hospital industry sources, when the DRG was first adopted many hospitals lost money doing IOL implants. Since the introduction of the DRG system, hospitals have taken steps to reduce their costs. Hospitals have reduced the average length of stay for this procedure from 3.2 days in 1981 to 2.2 days in 1984, and many hospitals are shooting for a one-day stay. Hospitals are also saving money by putting

Table IX

The Cost of Cataract Surgery

Location	Medicare Costs by Location: Facility Reimbursement	IOL Reimbursement	Physician Reimbursement	Patient Charges	Total Cost*
Hospital Impatient	$1200 (reimbursement set by DRG 39)	-0- (included in facility reimbursement)	$1200-$1500	$400 Part A Deductible $315 Part B $715	$3115 to $3415
Hospital Outpatient	$1300-$3800	$300-$900	$1200-$1500	$560-$1180 Part B	$3360 to $7380
Ambulatory Surgical Center (ASC)	$553 Maximum	$300-$900	$1200-$1500	$60-$180 20% of IOL	$2143 to $3153
Physician's Office	-0- (no facility reimbursement)	$300-$900	$1200-$1500	$375-$495 Part B	$1875 to $2895

* Total Cost does not include possible fees for assistant surgeons and anesthesiologists which may add over $500 to the bill. Such fees would usually be split between Medicare and the beneficiary, with Medicare paying 80%.

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their quantity lens purchases out for bid. Many hospitals have also standardized their supplies and reduced staffing costs. As a result many of the same hospitals are now breaking even or showing a modest profit from cataract surgery.

The prospective payment system is, for the most part, having its intended effect on the costs of inpatient cataract surgery. Hospital efficiency has been improved and costs contained. In theory this should save money and be advantageous for many patients. In practice, most cataract surgery is being moved to an outpatient setting (due primarily to recently imposed government policies), outside the realm of the DRG system, where costs are not controlled and great profits can be made, as is discussed in the following section.

3. Outpatient Hospital

When cataract surgery with lens implantation is performed on a hospital outpatient basis, the facility is reimbursed by Medicare part B on a cost basis at 80% of reasonable cost. There is no ceiling on what is considered reasonable. In addition the outpatient center passes on to Medicare the cost of the IOL, an item which is included in the DRG payment for the inpatient procedure. A recent look at actual invoices for hospital outpatients' facility charges from around the country ranged from $1684 to $4570. No figures are available to obtain averages. Example of bills can be found in Figures VII and VIII, on the following pages. These figures include the charge for an IOL which was $823. This $1684+ fee for the three-hour outpatient visit does not include the $1200+ in surgeons' and anesthesiologists' fees which are billed separately. So lucrative is the outpatient procedure that many hospitals are advertising "no cost" cataract surgery for Medicare patients, in which they waive the patient's $400 Medicare deductible. This practice will be discussed in detail in Section II E.

4. Ambulatory Surgical Centers/Free-Standing Surgical Centers (ASC)

An alternative to the hospital inpatient and outpatient settings is the free-standing surgical center or ambulatory surgical center (ASC). These usually are surgical centers designed specifically for cataract surgery and lens implants, which are usually shared by a group of physicians. Medicare pays a maximum of $553 in facility fees plus the cost of the lens. The beneficiary is required to pay 20% of the cost of the IOL. The charges to Medicare for lenses is comparable to the outpatient cost, ranging from $300 to over $900.

5. Physician's Office

At present, a handful of physicians are performing cataract surgery on an outpatient basis in their own offices. There is no reimbursement for facility fees when the procedures are performed in the office. In such cases, the surgeon is reimbursed only for the IOL and his operating fees.

Table X

Percentage of Procedures Performed in Each Treatment Setting

	Physician's Office & ASC	Outpatient Hospital	Inpatient Hospital
1981	-	-	-
1985	7%	70%	23%
1986	10%	75%	15%
1987	12%	80%	8%
1988	13%	79%	8%
1989	14%	78%	8%
1990	15%	77%	8%

Projections based on data that 5% of surgeons in 1985 performed opthalmic surgery in physician's offices or ASCs.

Figure VII

6320 Sherman Way
Canoga Park, CA 91306
(213) 348-0200

PATIENT NAME	ACCOUNT NUMBER	ROOM NO	START DATE	END DATE
STE			2/06/85	2/06/85

FINANCIAL CLASS	INSURANCE PLANS	STATEMENT DATE
I	1 3	2/16/85

GUAR. NA

CA. 91367 AGE C7C DOCTOR NAME

DATE	REVENUE CODE	DESCRIPTION CODE	RVS CODES	SERVICE DESCRIPTION	QUANTITY	PRICE
FINAL	TLI					
2/01	7[illegible]	0280000	93085	EXT PHOTO GRAPHY	1	[illegible]
2/01	7[illegible]	0280002	93980	ECHO-OPHTHALMIC A	1	[illegible]
2/01	7[illegible]	0280010	76515	ECHO-OPHTH TOPO SCAN	1	[illegible]
2/01	7[illegible]	0280024	67299	NEODYMIUM YAG LASER	1	[illegible]
2/06	920	0620002	0C59	MAJOR SURGERY HOUR	1	425.00
2/06	920	0620005	*	P C LENS	1	[illegible]
2/06	920	0620009		STERI-DRAPE 23660	1	[illegible]
2/06	920	0620017		MICROSCOPE UNIT	1	[illegible]
2/06	920	0620024	0099	ANGIOCATH ALL SIZES	1	[illegible]
2/06	920	0620031		SLEEVES	3	[illegible]
2/06	920	0620035		SCRUBS	3	[illegible]
2/06	920	0620049	0099	BULB SYRINGE	1	[illegible]
2/06	920	0620051		TOWELS &	1	[illegible]
2/06	920	0620054		SUTURE/EYE	2	[illegible]
2/06	920	0620121		MINOR PAK	1	[illegible]
2/06	920	0620126	0099	EYE CAUTERY	1	[illegible]
2/06	920	0620134	0099	EYE SHIELD	1	[illegible]
2/06	920	0620183	0099	HUMIDIFIER	1	[illegible]
2/06	920	0620194	0099	KERATONE BLADE	1	[illegible]
2/06	920	0620210	0099	LOCAL TRAY	1	[illegible]
2/06	920	0620236	0099	MICROSCOPE COVER	1	[illegible]
2/06	920	0620254	0099	OXYGEN MASK OR CANN	1	[illegible]
2/06	920	0620268	0099	PREP TRAY	1	[illegible]
2/06	920	0620324	0099	IV TUBING	1	[illegible]
2/06	920	0620370	0099	MECH CELLS/PACK	1	[illegible]
2/06	920	0620376	0099	BREATHING CIRCUT	1	[illegible]
2/06	920	0620676	0099	EYE FILTER	2	[illegible]
2/06	920	0620703		MICROSURGICAL KNIFE	1	[illegible]
2/06	920	0620719		CAVITRON PACK	1	[illegible]
2/06	920	0650037	0099	OXYGEN	1	[illegible]
2/06	919	0640152	0099	EYE PADS	1	[illegible]
2/06	919	0640152	0099	EYE PADS	1	[illegible]
2/06	924	0650010	85031	COMPLETE BLOOD CNT	1	[illegible]
2/06	924	0650023		PROCUREMENT FEE CHRG	1	[illegible]
2/06	924	0652030	84295	SODIUM	1	[illegible]
2/06	924	0652040	84132	POTASSIUM	1	[illegible]
2/06	924	0652050	82437	CHLORIDES	1	[illegible]
2/06	924	0657060	82820	CO2	1	[illegible]
2/06	924	0660015	BE3CG	GROSS CRLY	1	[illegible]

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Figure VIII

20800 Sherman Way
Canoga Park, CA 91306
(213) 348 0200

Out-pt.

PATIENT NAME	ACCOUNT NUMBER	ROOM NO.	ADMIT DATE	DISC. DATE	PAGE
EFFEN			2/06/85	2/06/85	2

FINANCIAL CLASS	INSURANCE PLANS	STATEMENT DATE
1	1 2 3	2/16/85

GRANTOR
NAME S
S
MI - ...ille CA. 91367

AGE
070

DOCTOR NAME

DATE	REFERENCE NUMBER	DESCRIPTION CODE	RVS CODES	SERVICE DESCRIPTION	QUANTITY	PRICE
FINAL BILL						
2/06	947	0160056	0099	VISTARIL IC 100MG	1	10.00
2/06	947	0160071	0099	FPL SCC OPTH	1	12.00
2/06	947	0160075	0099	MYDRIACYL 1% OPTH	1	20.00
2/06	947	0160075	0099	MYDRIACYL 1% OPTH	1	20.00
2/06	947	0160085	0099	PCLY-FRED OPTH SCC	1	12.00
2/06	900	0160200	0099	IV SOLUTN 1000CC	1	15.00
2/06	900	0160220	0099	IRR WATER 2000CC	1	10.00
2/06	900	0160660	0099	NSS	2	22.00
2/06	947	0160920	0099	GENERCL ALL DOSE	1	9.00
2/06	900	0160930	0099	DEPO-PROVCL 40MG/CC	1	17.00
2/06	900	0161670	0099	MIOCHOL OPH	2	30.00
2/06	947	0161833	0099	NEOSYNEPHRINE 10%	1	11.00
2/06	900	0162000	0099	PILOCARPINE 2%	1	9.00
2/06	900	0162520	0099	TETRACAINE OPH .5%	1	6.00
2/06	900	0162610	0099	MYCASE 150 USP	1	7.00
2/06	900	0162680	0099	AYLOCAIN ALL DOSE	2	13.00
2/06	900	0163328	0099	GARAMYCIN INJ 20MG	1	15.00
2/06	900	0163569	0099	MAXITROL OINT	1	11.00
2/06	947	0163589	0099	NEOSPORIN OINT .1 GZ	1	7.00
2/06	947	0163779	0099	MOBILL ICC	1	7.00
2/07	915	0020410		OP/SURG-DAY CARE 1HR	4	[illegible]
2/07	915	0020412		OP/SRG-DAY CARE 1/4H	2	13.00
				TOTAL AMOUNT DUE		4539.90
		SUMMARY OF CHARGES				
				SURGERY		576.00
				SURGICAL SUPPLIES		2008.60
				ANESTHESIOLOGY		3.50
				CENTRAL SUPPLY		1.00
				LAB- CLINICAL		144.80
				LAB- PATHOLOGICAL		9.00
				NON-EVASIVE EYE EXAM		1529.40
				PHARMACY		271.70
				SUMMARIZED TOTAL		4539.90

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[illegible] RETAIN THIS STATEMENT FOR YOUR RECORDS. A CHARGE WILL BE MADE FOR ADDITIONAL COPIES.

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Most experts predict that unless there is a policy change by HCFA or the Congress, 92% or more of all cataract surgery will be performed on a hospital outpatient basis by 1990. (See Table X, above) Hospitals have an incentive to keep their inpatient costs below the DRG level in order to stay in business and continue to provide services. Outpatient facilities, on the other hand, have been designed for maximum efficiency and minimal operating costs. They have reduced the two to three day hospital stay for inpatients to a three-hour hospital visit. Like the inpatient facilities, the outpatient facilities, often in the same hospitals, can purchase their lenses at volume discounts. Intuitively, one would think that these savings would be passed on to the patients and Medicare. This is not the case. Medicare under part B pays more, substantially more, for IOL implants performed in the hospital outpatient setting. Medicare is paying the hospitals about $1200 under DRG 39 for cataract surgery with IOL implants. These same hospitals are collecting several times this amount, as much as $4500, for the identical procedure using only 3 hours of hospital resources.

As mentioned earlier, standard quality IOLs can be purchased reasonably for as little as $90 by requiring manufacturers to bid on them. Medicare part B is reimbursing outpatient hospitals and ASCs between $300 and $900 per lens. This year for IOLs alone Medicare will overpay at least $160 million.

By allowing hospitals to receive much more money for performing outpatient IOL implants, HCFA is forcing cataract surgery into the more lucrative outpatient arena. This will dramatically alter the DRG system by raising inpatient hospital costs first by reducing the patient volume on which hospitals depend to keep their costs down, and second by leaving hospitals with extremely sick or frail patients. The DRGs were calculated based on the "typical" patient. These sick and frail patients are much more costly than the "typical" patient, and hospitals cannot afford to treat them under the current DRG system. Unless the Medicare law is changed there is no incentive to contain costs of this procedure which will waste at least $1.2 billion this year, and will lose many billions more.

Additionally, patients operated upon in an inpatient setting receive extra protection because Peer Review Organization review all cataract preadmissions. Hospitals have formal internal peer review and other safeguards to insure quality of care. To some extent, these safeguards exist in hospital outpatient settings, but they are much less prevalent in ASCs or non-hospital outpatients surgical locations.

C. Kickbacks, Discounts, Bonuses, and Rebates

Section 1877 of the Social Security Act makes it a felony to offer or solicit bribes, kickbacks or rebates in cash or in kind unless "the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider..." Although the law encourages industry promoted discounts on items such as IOLs, what is prohibited is the failure to disclose the discount and pass it on to the Medicare program.

The climate which stimulates kickbacks and other improper inducements relates directly to the price of the IOL and Medicare reimbursement practices relating to the IOL. It is worth repeating that the average price of an IOL reimbursed by the Medicare program in 1981 was $265. In 1985, it was $400. The manufacturing cost for an IOL is roughly $35-$50. Under the DRG system many hospitals have gone to competitive bidding, reducing IOL prices by as much as 50%, or less than $100 apiece. Where outpatient surgery is performed, there is no corresponding pressure to reduce IOL prices since under part B of Medicare, the insurance carrier pays the invoice price of the IOL which ranges from $300 to $750. It is obvious that the profit margins are very high and that some manufacturers are trying to stave off true competitive bidding by taking $50 or more out of their profits to "buy off" some physicians and gain a competitive edge.

Evidence of kickbacks and other improper inducements have been associated with the IOL industry for more than five years. From the Subcommittee's investigation, evidence and allegations of kickbacks and other illegal marketing practices are flagrant and inescapable. Inducements ranged from:

- outright payments of cash to physicians (in the form of a $50 to $70 deposit in a private account in the Cayman Islands) for each IOL purchased,
- "free stock" in the manufacturer,
- "free lasers" and other IOL surgery equipment,
- "donations" of one lens for every on a purchased,
- keys to resort condominiums,
- yachts, cars and houses,
- trips to Colorado, Europe, etc. for "medical" skiing seminars, and
- large payments for phony consultants.

Our investigation verified the judgement of one physician who told the Subcommittee, "The whole system is corrupt and is corrupting physicians, mostly I feel, out of ignorance — but of course greed is a big factor. Some very big names in ophthalmology are receiving large financial incentives to PR the companies implants. I'm happy to see you investigating this and though it casts a shadow on my profession — if we can stop the 20% or so who are unethical it may restore people's faith in my profession."

What is a Kickback?

Title 42, section 1395 of the U.S.Code defines a kickback as follows:

(a) Whoever —
(1) knowingly and willfully makes or causes to be made any false statement or representation of a material fact in any application for any benefit or payment under this subchapter.
(2) at any time knowingly and willingly makes or causes to be made any false statement or representation of a material fact for use in determining rights to any such benefit or payment.
(3) having knowledge of the occurrence of any event affecting (A) his initial or continued right to any such benefit or payment, or (B) the initial or continued right to any such benefit or payment of any other individual in whose behalf he has applied for or is receiving such benefit or payment, conceals or fails to disclose such event with an intent fraudulently to secure such benefit or payment either in a greater amount or quantitiy than is due or when no such benefit or payment is authorized or
(4) having made application to receive any such benefit or payment of the use and benefit of another and having received it, knowingly and willfully converts such benefit or payment of any part thereof to a use other than for the use and benefit of such other person, shall (i) in the case of such statement,

representation concealment, failure, or conversion by any person in connection with the furnishing (by that person) of items or services for which payment is or may be made under this subchapter, be guilty of a felony and upon conviction thereof fined not more than $25,000 or imprisoned for not more than five years or both, or (ii) in the case of such a statement, representation, concealment, failure, or conversion by any other person, be guilty of a misdemeanor and upon conviction thereof fined not more than $10,000 or imprisoned for not more than one year, or both.

(b)(1) Whoever knowingly and willingly solicts or receives any renumeration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind —

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which may be made in whole or in part under this subchapter, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under this subchapter, shall be guilty of a felony and upon conviction thereof,shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

(2) Whoever knowingly and willfully offers or pays any renumeration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person —

(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under this subchapter, or

(B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under this subchapter, shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

The existing kickback statute, detailed above, was modified in 1978 by Public Law 95-142. Based on congressional investigations demonstrating the impact of fraud, waste and abuse in clinical laboratories, Medicaid mills and nursing homes, penalties for kickbacks were extended from a misdemeanor to a felony. The legislative history of what constitutes a felony is more specific as to what constitutes a kickback:

> "Kickbacks take a variety of forms including cash long-term credit arrangements, gifts, supplies, and equipment, and the furnishing of business equipment."

Specific evidence of inproper inducements found by the Subcommittee have been or will be referred to the Inspector General of the U.S. Department of Health and Human Services for investigation. What follows is not exhaustive, but rather illustrative of the typical kinds of conduct brought to the Subcommittee's attention.

Direct Kickbacks

- Three ophthalmologists told the Subcommittee that they participated in direct kickback schemes in which they were given direct cash rebates from the manufacturers for every lens that they implanted.

- A well known surgeon, according to one investigation received 1600 free lenses in return for using his name in marketing the lens. He then billed Medicare $500 to each of these lenses. Medicare paid $80,000 too much just for IOLs.

- A California ophthalmologist told the Subcommittee that he declined to participate in a purchase arrangement commonly used by IOL manufacturers. He said, "A company offered me $70 per lens to be put into an account in my name in the Bahamas — I told him to ___ up a rope".

Indirect Kickbacks

The Subcommittee found the kickbacks are often disguised by salesmen as follows:

- Gifts of stock in the manufacturer;

- Use of a yacht;

- Discount of physicians for volume purchases of IOLs which are not made available uniformly to all physicians;

- Cash rebates to physicians who purchase from the company;

- Free IOLs provided by the manufacturer.

Of these mechanisms, the award of stock is commonly offered by IOL manufacturers, according to an ophthalmologist who told the Subcommitte he was offered such inducements for purchasing IOLs from the company.

A securities analyst with a investment firm verified the ophthalmologist's claims in a telephone conversation with the Subcommittee in April of 1985. She said, "One IOL company owned by doctors, blatantly offers stock and other inducements to doctors." She continued, "This cannot be reflected in lower Medicare prices." The American Academy of Ophthalmology, in a recent advisory opinion on their code of ethics, reported that receiving shares of stock in exchange or volume purchases of lenses is patently unethical. The advisory stated, "Not only would it be impossible to pass on to the cataract patient the fluctuating value of the stock received, a doctor could be easily seduced into a continuing loyalty to the company in question."

An ophthalmologist reported to the Subcommittee in July, 1985 that, "several years ago a company offered use of a yacht off Florida as an incentive to use their lenses."

Another ophthalmologist mentioned he was offered a "second"home — purchased by the company seeking his business.

One manufacturer informed the Administrator of a southern hospital that for every "ultraviolet absorbing IOL purchased at list price, a free "generic" posterior chamber lens would be donated to the hospital." (See letter dated 1984 outlining the proposal, in Figure IX.)

Business Equipment

The most common form of inducement offered is surgical and/or other equipment commonly used by an ophthalmologist. Such equipment often includes:

YAG Lasers. Lasers come in handy if a posterior implant patient finds that the capsule around his/her new lens has clouded up, something that happens about half the time. By focusing the laser on the capsule, the physician can tear a hole in the membrane, much like pulling a curtain back from a window, and restore vision. Lasers can cost as much as $80,000-$90,000 to purchase. (Manufacturers cost is $8,000)

Surgical accessories or surgical packs. Surgical accessories commonly include a disposable syringe filled with Healon or other clear liquids which help maintain the shape of the eye during surgery, and disposable sponges and knives. The pack is worth abut $75.

Phacoemulsification machines are devices which use ultrasound vibrations to turn cataracts into a jelly-like substance before extraction. They cost around $1000 per month to lease, or about $35,000 to purchase.

In most cases, the equipment mentioned above is essential to cataract surgery and follow-up care. Questions of concern arise, however, when such equipment if offered as an inducement to do business with a particular IOL manufacturer without consideration of what would be in the best interest of the patient or without reflecting those savings to the Medicare program. Furthermore, tax laws may be violated because hospitals and doctors are encouraged by manufacturers to take depreciation and investment tax credit on equipment that they really did not buy.

The legitimacy of these concerns was documented extensively in the Subcommittee's investigation.

According to the Executive Director of the American Intraocular Implant Society, in a recent Barron's interview, "how is a hospital supposed to reflect a YAG laster when they're getting a flat fee?"

This official takes a stern view of any form of discount which cannot be reflected in bills and said he is well aware of the problems of kickbacks in the IOL business. "I get calls all the time from doctors who asked me if they can accept a YAG laser. I tell them, 'Pay for the damn thing yourself.'" He said physicians also asked whether they can accept free surgical packs. "Our position is that any savings to a hospital or a doctor must absolutely be reflected in their bills."

A former President of the Amercain Intraocular Implant Society, addressed the notion that some programs seem designed by the manucfaturers to facilitate criminal

Figure IX

, 1984

Administrator
Hospital

Dear

The following is a purchase agreement for the sale of intraocular lenses to Hospital.

Prices are only for lenses purchased and used by that hospital. This agreement is voided by the distribution of products by Hospital to other facilities.

Prices are guaranteed for a period of one year starting December 1, 1984 and terminating November 30, 1985.

will initiate a consignment of lenses at that hospital.

PLAN A

With each ultraviolet absorbing IOL purchased from at list price, a free "generic" posterior chamber lens will be donated to Hospital. These generic lenses include catalog series 01, 02, 00, and 04. -loop, lens, and UV lenses are not included in the styles eligible for free lenses.

Free lenses will be reimbursed on a monthly basis.

PLAN B*

will sell IOLs to Hospital at the following prices:

Styles 00, 01, 02, 04 (generic)	$232.50 each
PLUS one free I/A tube-set with each purchased lens	-32.50 value
PLUS one free pair of UV post-op goggles with each lens	- 5.00 value
	$195.00 net cost

Figure IX (cont.)

Style UV series (ultraviolet absorbing lens)		$280.00
PLUS one free	I/A tube set	-32.50
PLUS one free pair of UV goggles		- 5.00
		$242.50 net cost

*There are no minimum usage requirements with PLAN B.

PLAN C

will sell IOLs to Hospital at the following prices, providing the minimum monthly ordering quantities are observed.

Minimum of 50 lenses/month*

Generic styles 00, 01, 02, 04	$170.50 each
UV style posterior chamber lenses	262.50 each

Minimum of 75 lenses/month*

Generic styles 00, 01, 02, 04	$155.00 each
UV style posterior chamber lenses	245.00 each

Minimum of 100 lenses/month*

Generic styles 00, 01, 02, 04	$139.50 each
PLUS one free UV post-op goggle	-5.00
	$134.50 net cost
UV style posterior chamber lenses	$199.50 each
PLUS one free UV post-op goggle	-5.00
	$194.50 net cost

*Lenses ordered can be mixed in any quantities or product styles.

RESIDENT PROGRAM

is extremely committed to the education growth of Ophthalmology residents. Upon initiation of PLANS A, B, or C, will provide a $5,000 fund for use by the residents of the University for the following uses: travel to and from major meetings, travel and/or honorariums for guest lectures, other educational reasons approved by

This fund can be renewed annually. The fund will be maintained by and withdrawals must be requested in writing.

Figure IX (cont.)

BONUS - When the first two hundred lenses are reordered from the consignment, the Video Textbook of Cataract Surgery (see attachment) will be donated to the Residency Program. This excellent teaching tool is valued at $800.

Warmest personal regards,

deception by surgeons and reimbursers. "If you get a free piece of equipment, how can you prorate that free piece of equipment onto the cost of each cataract operation which you put an IOL in and show that discount to Medicare? I don't know how you can do that."

- A Maryland ophthalmologist wrote the Subcommittee that an IOL company offered to provide a free phacoemulsifier to his center if they agreed to use a certain number of their IOLs. His department declined.

- A South Dakota doctor was offered over $95,000 worth of equipment in exchange for a 3-year commitment to use IOLs from a particular manufacturer. He was also offered a camera and VCR. He told the Subcommittee, "I was told that this inducement was approved by Medicare and the American Implant Society and that I would get an investment tax credit on the equipment. All of this is untrue, I realize. Now tell me, how am I going to get an investment tax credit on equipment I didn't purchase and Medicare essentially pays for?"

- The vast majority of ophthalmologists responding to a June, 1985, Subcommittee questionnaire reported they were offered equipment at discount or free, including lasers, cameras, VCRs, slit lamps, etc. some of which is related to cataract surgery and some of which is not.

Travel and Training

Another common inducement made by IOL manufacturers to agreeable doctors involved the arrangement of travel on the pretext of "training seminars." According to the American Academy of Ophthalmology's (AAO) code of ethics, such "customer appreciation plans" under which they invite all ophthalmologists who purchase ..(a quantity).. of lenses in any year to be guests of the IOL manfacturees for an all-expenses-paid week long meeting of the IOL manufacturer in the Bahamas..." is simply a bribe or a kickback. As stated in the AAO's code of ethics: "Window dressing seminars do not transform a free vacation in the Bahamas into a scientific conference which is paid for by the ophthalmologist ..."

In spite of the AAO warnings, such inducements abound in the industry three ophthalmologists told the Subcommittee that IOL salesmen told them they would be awarded vacations for purchasing a certain number of IOLs.

Telephone conversations between Subcommittee staff and a number of ophthalmologists revealed that companies offer travel in Europe in appreciation of the purchase of a large volume of IOLs.

A Counsel for the American Intraocular Implant Society reported to the Subcommittee, "Many doctors have complained to me about certain companies (names deleted) using "studies" as excuses to provide doctors who use their lenses with free trips."

Again, it is important to note that free travel is not automatically illegal for the lens manufacturer to provide or for the implant surgeon to receive, as long as they are reflected in reimbursement claims. According to the American Intraocular Implant Society, however, such bonuses raise serious legal and ethical questions and should be avoided.

Paid IOL Investigators

The principal barrier to entry in the IOL market is FDA approval of IOLs (see Section VI A for further detail). This has not been a major problem because of a special provision in the IOL device law which allows distribution of IOLs to qualfied surgeons on an almost unlimited basis prior to approval. In order to use the lens, a surgeon agrees to serve as an "investigator" for an IOL manufacturer and track patients who have the IOL inserted (called a "core" study). The doctor is paid compensation for his work by the manufacturer. Literally every board certified ophthalmologist is eligible to participate in this investigative process.

In a perversion of the FDA process, some IOL manufacturers are using the FDA approval process as an excuse to "buy off" surgeons. Manufacturers are paying very large amounts for paperwork preparation and also designating some doctors as adjunct investigators and paying them for essentially nothing but the use of the manufacturer's lens.

This legal form of "kickback," sanctioned by current FDA law, works essentialy as

follows: The FDA requires a "core" study of 500 patients to be followed over one year. This means a manfacturer has to arrange for 800-1,000 patients to be treated by about 25-50 doctors. The doctors can be paid for acting as an "investigator" and filing 6 brief reports on each patient. Some manufacturers pay cash; some give free lenses. One free lens ($300) is roughly about value for total work done on one patient. Many manufacturers pay far in excess of this. They are really bribing doctors.

FDA also allows "adjunct" study beyond core requirements. There is no paperwork involved; FDA admits they don't use the data submitted. By applying for adjunct status, a manufacturer can sell lenses to these "investigators" without FDA final approval. This is another vehicle for bribery. Furthermore, some manufacturers are expanding their studies to thousands as a way to use FDA as a legal excuse to make high payments etc. to doctors using their lenses.

Sale and Resale of IOLs by Surgeons

A more sophisticated and subtle form of improper inducements exists in the sale and resale of IOLs by surgeons and referral they make to individuals and hospitals who will use these IOLs.

One scheme involves surgeons purchasing the lenses they use directly from the manufacturers, and then reselling the IOLs to the hospitals, who then bill Medicare directly. Medicare reimburses the hospital based upon their costs, which in many cases are considerably more than the surgeon paid for them. The surgeon may mark up the lens directly, or he may participate in any one of a number of discount or rebate schemes, which provide him with financial incentives which do not show up on the invoice.

Surgeons may profit even without purchasing the lenses directly. Manufacturers offer the same "bribes" to ophthalmologists who have the hospitals order the manufacturer's lenses. This makes the Medicare overpayments even more difficult to track down.

LIBRARY NOV 1980

D. "No Cost" Advertisements

In recent months, advertisements offering "no cost" cataract surgery to Medicare patients have been appearing in magazines, newspapers, and mailboxes around the country. "No cost" cataract surgery is not free; Medicare winds up footing the entire bill, while the facilities and physicians waive the patient's deductible. "No cost" cataract surgery is of no cost only to the patients.

The ad below explains how "no cost" cataract surgery works. According to the ad, Medicare now allows 100% reimbursement of surgeon's fees for outpatient cataract surgery if the surgery is performed in an approved outpatient surgery center and the surgeon accepts Medicare assignment. Medicare pays 80% of the hospital bill, with the patient or his coinsurance responsible for the remaining 20%. Many hospitals waive or discount this 20%, saving the patient $400 or more in out of pocket expenses. One hospital reported increasing business by over 11% and annual revenue by over $100,000 after instituting a "no cost" surgical program.

One California hospital did a cost-benefit analysis after instituting "no cost" cataract surgery and sending out brochures to 9000 area residents in a direct mail advertising campaign. Cataract surgery cases at the hospital increased by 11%, but the number of Medicare patients increased by 15%. Now over 90% of the hospitals cataract patients are covered by Medicare. Previously the hospital had been reimbursed $1463 per case under the DRG for inpatient surgery. Under the "no cost" scheme they are collecting $1490 per case, and that is without incurring the 24-hour nursing costs associated with inpatient surgery. In addition, 80% of their patients had supplementary private insurance and the hospital was able to collect a major portion of the patient's $601 coinsurance and deductible. In short, for every dollar the hospital spent for its mail campaign, they increased revenues by over $30.

Introducing the Senior Citizens Courtesy Program:

Outpatient cataract surgery in a hospital setting at no cost to you!

Financial problems shouldn't be a barrier if you need cataract surgery. Here's how our office can help.

Medicare now allows 100% reimbursement of surgeons' fees for outpatient cataract surgery if the surgery is performed in an approved outpatient surgery center and the surgeons accept Medicare assignment. *Our surgical team does accept assignment.*

If your surgery is performed in a hospital outpatient surgery center, Medicare pays 80% of the hospital bill, with the additional 20% covered by any co-insurance or supplemental insurance you may have. Should you have Medicare coverage only, we have an agreement with Garland Community Hospital to discount this 20%. The hospital will also discount any co-insurance deductible. In either case, you have no cost.

You have the security of a hospital setting.

We prefer the outpatient surgery center at Garland Community Hospital, whose operating rooms are well equipped for all types of ophthalmic surgery. In the unlikely event that an emergency should occur, you'll be in the right place for immediate treatment. That can be reassuring.

Our office has state-of-the-art equipment.

Our Ophthalmology Center provides complete eye care for the whole family.

In addition to cataract and intraocular lens implant surgery, we offer eye exams, contact lenses, treatment of glaucoma and other eye diseases, and laser surgery. Our in-office technology includes an Argon Laser as well as the new YAG Laser for office treatment of secondary cataracts.

If you have any questions about the Senior Citizens Courtesy Program, or eye care in general, or would like to make an appointment, call us at one of the numbers listed.

HOW THE PROGRAM WORKS

Fees for Surgeons and Associate Surgeon	100% Covered by Medicare
Fee for Anesthesiologist	100% Covered by Medicare and Co-insurance
If your hospital bill is	$2,000.00
Medicare would cover 80%	$1,600.00
You would owe the 20% Medicare co-payment	$ 400.00
Garland Community Hospital discounts this amount	- $ 400.00
So you owe nothing!	-0-

We accept Medicare assignment.

We routinely accept Medicare assignment for all office visits. This means you are only responsible for 20% of the approved fee after the yearly deductible has been met. In certain hardship cases, this amount can be waived.

ATTENTION VETERANS:

Our Senior Citizen's Courtesy Program can especially valuable to you. You can now have needed cataract/implant surgery without any out-of-pocket expense, without any delay in scheduling, and without having to go to a veteran's hospital.

BEST COPY AVAILABLE

There is no prohibition against waiver of deductible and coinsurance by a provider of services. This ability to waive copayments applies to both inpatient and outpatient service and is not affected by whether the provider receives cost-based reimbursement or prospective payments. However, the provider, and not Medicare, must bear the beneficiary's liability. For purposes of determining Medicare payment, the provider must bill its intermediary as if the patient were billed for the appropriate deductible coinsurance amounts which are deducted from the prospective payments. Under cost reimbursement, these amounts must be included on the provider's cost report for the determination of final payment for the year. The provider may not claim as a bad debt amounts for which it assumed the beneficiary's liability. A provider's waiving of payment from the beneficiary should have no effect on Medicare payments. Unfortunately, this has not been the case.

Current Medicare program instructions indicate that a billed amount that is not reasonably related to an expectation of payment should not be considered the "actual" charge for processing a current claim. What this means is that if hospitals and physicians set charges for services, fully intending to waive the patients deductible and coinsurance, they are in violation of the law if they submit those set charges to Medicare as the "actual" charges.

The ads on the following pages, collected from newspapers around the country, are representative of this widespread fraudulent practice. "No cost" cataract surgery is responsible for millions of dollars in Medicare overpayments. Hospitals are inflating their charges to Medicare by an amount equal to or greater than the patients coinsurance and deductible, with the full intention of waiving the patient's costs and having Medicare foot the entire bill. Not only are these hospitals openly violating the congressional intent of the Medicare system, HCFA is condoning their actions by failing to take action against them.

Waiver of beneficiary copayments represents a clear disregard for Medicare and the philosophy behind Medicare coinsurance and deductibles. The Medicare program requires patients to share in the cost of their health care for a number of important reasons. First, this cost sharing reduces the portion Medicare must pay,which would otherwise be financed through taxes and other sources. Cost sharing also reduces, but does not eliminate, the need for administrative control over the use of medical services by providing a financial incentive to patients and providers to choose more economical forms of care.

The Subcommittee would in fact support the charitable waiving of copayments for those elderly to whom this represents a burden. It cannot, however, condone the waiving of coinsurance when done explicitly to entice unneeded cataract surgery or as a method of bilking the Medicare program.

BEST COPY AVAILABLE

FREE
Cataract Surgery?
What's the catch?

Seeing is believing. Now FREE Cataract Surgery is available for Medicare recipients.

Same Day Surgical Services has taken advantage of advanced medical technology to greatly simplify the treatment of cataracts and speed up recovery.

Jerry Zeiman, MD, our board certified ophthalmologist, performs the cataract surgery at Ceder Medical Center on an out-patient basis. And a staff of fully trained professionals are with you every step of the way. From the time you first come to our convenient Miami Beach office for a FREE consultation, through surgery and afterwards, too. We can even provide FREE transportation to and from our office as well as the hospital, if you need it.*

More than 1000 patients have taken advantage of our simplified, FREE cataract surgery. If now's starting to see the world around you become fuzzy or blurry, you could have the early symptoms of cataract. Call today.

FREE Cataract Surgery for medicare recipients – NO initial consultation cost, NO hospital bills, NO doctor bills. PLUS 1 FREE pair of glasses and FREE transportation, those to desert*

SAME DAY
SURGICAL SERVICES, INC.

There's no reason to suffer from CATARACTS.

A cataract is a simple clouding of the lens of your eye. But left untreated, cataracts can cause a gradual loss of vision. There's no reason to suffer from cataracts, because they can be corrected by a short, simple procedure.

The only hospital in the state specializing in the treatment of eye and vision disorders, the Eye Foundation Hospital in Birmingham is making a special offer to you, to celebrate our 20 years of service to the people of the Southeast! Now, through the end of May, The Eye Foundation Hospital will waive the $400 Medicare deductible you would ordinarily pay when you're admitted to the hospital for cataract surgery.* Our eye doctors will also bill Medicare for full payment for your first office visit and cataract screening. That means you can have your eyes checked for cataracts, and have them corrected if need be, with virtually no out-of-pocket hospital expenses!

Additionally, you'll receive a comprehensive pair of eyeglasses from the Eye Foundation Hospital optical dispensary. If you don't already have an eye doctor, we'll be happy to refer you to a qualified ophthalmologist.

If your eyesight isn't what it used to be, don't assume it's just part of growing older. For your free cataract screening, call the Eye Foundation Hospital today at:

325-8272

BEST COPY AVAILABLE

Don't Let Cataracts Steal Your Joyous Moments
Because Your Eyesight is Priceless...
Convenient Outpatient Cataract Surgery in the Safety of Sutter General Hospital at No Cost To You
Sutter General Hospital
(916) 453-1302
"I Can See."
No Cost Cataract Surgery
You can't afford cataracts.
Community Eye Center
442-EYES
You can't afford to miss our "Gift of Sight."
1-800-556-3400.
Senior CARE

BEST COPY AVAILABLE

III. A SURVEY OF OPHTHALMOLOGISTS REGARDING THEIR EXPERIENCES WITH FRAUD, WASTE AND ABUSE IN THE AREA OF CATARACT SURGERY

As a part of its comprehensive review of Medicare cataract surgery, the Subcommitee sought to systematically gather the opinions of those directly providing this service. Subcommittee staff had meetings, telephone conversations and written correspondence with, among others, physicians performing cataract surgery, the professional associations which represent ophthalmologists, IOL manufacturers and their sales representatives, and hospital officials. The Chairman also conducted a national random survey of ophthalmologists performing cataract surgery and of the industry manufacturing IOLs.

Information from providers confirmed other evidence gathered by the Subcommittee of the widespread nature of fraud, waste, and abuse surrounding cataract surgery and in particular the sale of intraocular lenses.

In June, 1985, the Chairman mailed a survey to a statistically valid random sample of doctors performing cataract surgery in the United States. This survey asked ophthalmologists a series of questions focusing on marketing practices and purchasing agreements in the sale of intraocular lenses. (See Appendix A). Doctors from around the nation, representing nearly one million patients, responded to the Chairman's survey.

While most of those doctors responding to the survey indicated that they themselves were not involved in such practices, many reported to the Subcommittee that they were familiar with a number of questionable and/or illegal purchasing arrangements employed by IOL manufacturers/sales representatives. Many doctors reported being aware of:

- awards of vacations to physicians for purchasing a certain number of IOLs,
- gifts of stock in the manufacturing company to physicians who purchase a number of lenses
- cash rebates to physicians who purchase lenses,
- free IOLs for purchase of a certain number of IOLs, and
- progressive discounts for volume orders.

Other doctors reported having knowledge of specific offers made to peers by IOL manufacturers and/or their sales representatives for the purchase of certain numbers of their lenses including:

- purchasing of second homes for doctors,
- cash payments of up to $150 per lens purchased,
- use of a yacht off the coast of Florida,
- free phacoemulsifiers (valued at approximately $35,000), and
- free vitrectomy machines (valued at approximately $20,000).

While most doctors responding to the Subcommittee survey indicate that such practices are not offered by manufacturers with which they do business, roughly one third reported that they knew of such offers by their manufacturers. Additionally, roughly one third of the ophthalmologists responding to the survey reported having at one time or another declined participation in purchase arrangements such as those above.

The Subcommittee questionnaire also asked ophthalmologists whether they considered these types of purchasing arrangements to be improper or illegal inducements. Over two thirds of the respondents did consider such practices kickbacks, bribes, or something otherwise improper. Many also remarked on what they felt to be the unethical nature of such practices.

One third of the doctors responding told the Subcommittee that they did not consider these arrangements to be kickbacks, bribes, or other improper inducements. The majority of doctors responding in this manner considered these purchase agreements legitimate business offerings. Said one doctor, "It's the American way... You get what you can." Another responded, "Incentives are used by everyone to sell as encouragement to go a particular direction. Even my preacher cajoles, 'Come to church and go to heaven. Would you consider that a bribe?"

BEST COPY AVAILABLE

Ophthalmologists were asked whether they felt that IOL manufacturers and/or sales representatives *should be free to offer incentives to physicians* to purchase a particular brand of lens. A two-thirds majority of those doctors responding told the Subcommittee that this should not be allowed. One doctor replied, "We should purchase the lens we feel is best for use, not financially best for us." Another stated that such offerings "compromise quality of care." Still another felt these practices "cheat Medicare and the patients."

One third of the responding doctors felt that manufacturers and their representatives should be free to offer incentives. Some expressing this viewpoint felt strongly about their rights in a competitive market. One doctor told the Subcommittee, "Since medicine and physicians are now expected to be merchants, why not the same low standard of ethics as car salesmen?"

During the course of its investigation the Subcommittee was contacted by a number of provider representatives expressing concern over what they considered illegal or unethical inducements in the sale of IOLs. Knowledge of the existence of such practices within the ophthalmology profession is extensive. This spring one professional association held a symposium with a keynote address by the president of the group entitled, "Marketing Practices and Rebates That are Occurring and are Continuing to Occur, and Your Responsibility and Your Vulnerability." The president continues, "Discounts, rebates and bonuses have recently taken many forms ... free lenses ... free equipment ... cash payments ... Some of these programs seem designed by the manufacturers to facilitate criminal deception by surgeons to reimbursers ... To profit illegally from discounts, rebates or bonuses by failing to report them to government reimbursers ... subjects the entire profession to injury. These practices amount to welfare cheating."

The Subcommittee has been contacted by provider representatives who have been shocked by the nature and extent of kickback and bribe offerings and acceptances related to Medicare cataract surgery. One hospital representative stated, "IOL manufacturers and their sales representatives are committing wholesale fraud."

IV. A SURVEY OF THE IOL INDUSTRY REGARDING THEIR EXPERIENCES WITH FRAUD, WASTE AND ABUSE IN THE AREA OF CATARACT SURGERY

The Subcommittee also sent questionnaires to manufacturers of intraocular lenses. These surveys asked manufacturers a series of questions centering around their marketing practices surrounding the sale of IOLs. (See Appendix B) Among the areas of inquiry contained in the Subcommittee questionnaire were the basis of earnings of their sales representatives (salary and/or commission), incomes of the manufacturers and their sales representatives, types of marketing practices used and the reasons for using such practices, and manufacturer opinions as to the legality of properness of offering certain inducements for the purchase of a particular brand of IOLs.

As of this writing, the Subcommittee has received responses from 7 manufacturers with total 1984 gross sales of intraocular lenses of over $80 million. These companies employ marketing staffs made up primarily of sales representatives averaging 45 full time workers.

Responses to the Subcommittee survey indicate that IOL sales representatives earn large salaries and that most work strictly on a commission basis. Average salaries of those selling IOLs for the 7 responding manufacturers range from $35,000 to $90,000. Six of the seven companies employ their salesmen on a commission basis only.

The majority of manufacturers responding indicated to the Subcommittee that they had knowledge of a range of marketing plans including the offering of free equipment, company stock, vacations, cash rebates and volume discounts. Several of the respondents provided the Subcommittee with lists of those of their competitors they suspect or know use these practices. The majority of these respondents indicated their distaste for such practices.

Several of the companies did indicate that they offer volume discounts and purchase credit plans, but that they instruct those doctors and hospitals taking part in these offers to indicate the reception of these discounts on their Medicare bills.

The IOL industry is a very competitive one. When asked why manufacturers employed these sales techniques, most companies responded that this was a necessity of the competitive marketplace. One large manufacturer responded, "The IOL industry is very competetive. Because of this competition, manufacturers work hard to be the supplier of choice. Because most manufacturers hold high product quality standards, manufacturers also compete with service, convenience, image and price." Another company indicated the corresponding pressure on a company to offer inducements, "A company which does not offer such discounts would likely lose the customer."

During the course of its investigation, the Subcommittee was regularly contacted by members and representatives of the IOL industry. Subcommittee staff conversations with sales representatives wishing to remain anonymous for fear of retribution provided a good deal of candid information. These salespersons described literally hundreds of instances of kickbacks and bribes and other schemes offered by themselves and their competitors. The most common of these inducements came in the form of cash rebates per lens (up to $150) going toward the purchase of durable medical equipments such as lasers and microscopes. One sales representative called this practice "Green Stamping," likening it to the collecting of stamps to purchase a gift when you have enough collected. These representatives also described schemes invoving free trips to Hawaii, paying for architects to design surgical centers, and even free vacation homes.

These anonymous salespersons also related to the Subcommittee stories of training sessions employed by certain manufacturers. "Ask them (doctors and hospitals) what it will take for them to buy from and give it to them. It doesn't matter what it takes," one salesperson reported being instructed in a training session by a previous employer.

The problem of fraud and abuse is a growing one according to most of those salespersons confiding with the Subcommittee. "It's just like the 55 miles per hour speed limit," commented one representative. "Doctors see their peers doing it, profiting from it and not getting punished, so they say 'Why not me?'"

V. A CANDID CONVERSATION WITH AN IOL SALESMAN

Reprinted below is an excerpt from an interview between three sellers of ophthalmology supplies and equipment, including intraocular lenses, and an ophthalmologist. Because receipt of this tape was conditioned on confidentiality, names and specific references have been omitted or changed to protect participants' identities. The salesmen are employed by one of the country's largest suppliers of ophthalmlogy goods. This conversation took place in May and June, 1985.

Enticements

Salesman: What we do, Dr. (name omitted), we establish a competitive price. And we take a portion of that price ... counts for more than let's say half of the lenses and give it back to you as purchase credits — so that you can apply it towards this, you can apply it toward (brand name omitted) ... well, another example. We have a video system right now — I don't know if you've got a video camera on your scope or not — it's a hell of a system ... The camera alone usually sells for $8495. Right now the camera's on for $6995. You can get a VCR, a monitor and a stand that it all fits on for $8495. So in essence you're getting about $1500 worth of video equipment at no charge. That's going to be on a limited time basis.

The Pitch

Salesman: ...what we need to do is sit down with you and get some figures from you so we can put together a package and start talking — and say, here are your equipment needs, here's basically how you can finance over the next 1, 2, 3 years.

What we came up with is a financing program that's based upon you using our consumables, okay? Since we have capital equipment on one side, which is state of the art and pretty much the industry standard, and then we have high quality consumable products, such as IOLs, contact lenses and pharmaceuticals, we put the two of them together to come up with a financing program so that you can high tech your office or get that capital equipment that you need without any cash outlay. Now, one of the reasons that we can do this is in the past we'd always been calling on hospitals, doctors' offices, pharmacy — all these different places. Now all of a sudden we can call on one facility like yours — an ASC — and sell all our products at that one point. We call it single point distribution, okay? By us being able to sell a lot of products to one facility like yours, we're able to lower our cost to serve — cost to serve the manufacturer, marketing, and so on down the line. Well, when we lower our cost to serve, we increase revenues. One of the ways we're using increasing revenues is giving it back to you in the form of earned purchase credits. Now earned purchase credits are credits based upon the gross profit margin of each item that you buy from us. So, take as an example, if you bought a (brand name omitted) lens from us, you'd earn a purchase credit on that, so you know that might be $2.50 or something. What we're doing is we're looking at earned purchase credits on all the products that you can buy from (company name omitted) — from that consumable side — the disposables, the IOLs, the contact lenses, pharmaceuticals.

Additional Benefits

Doctor: Okay, you say you can get investment tax credit right up front, entitled to it, right?
Salesman: Yep.
Doctor: And depreciation on it?
Salesman: Yep.

Purchase Credits: One Doctor's Arrangement

Salesman: So you're at $27,000 the first year, $31.8 (thousand) the second and $36.6 the third.
Second Salesman: For a total of $95,760. Now let me explain how you can use that. What we've done is we've projected out what you would earn over the next three years from us in purchase credits by simply using our products. If you chose to exercise all your credits today, you would have $95,000. Now, since this is a financing program, there is an interest charge on this. The interest charge works this way. In year one, if you only chose to exercise your purchase credits of $27,000 in year one, there'd be no interest charge. If you want to exercise two years' worth of purchase credits, there's a five percent interest charge. Year three there's a 10 percent interest charge — on the total amount of earned purchase credits that you choose to exercise ... Now, here's another thing that you need to think about. The equipment that you asked for — the the (brand name omitted) system, and the argon laser — that comes out to about $60,000. Because we have so much room to work with, that ten percent interest could be paid by

using earned purchase credits. So what I'm telling you is that you could get your (brand name omitted), your argon laser — we've covered the interest charge — and you could get all that with no cash outlay. Does it all make sense to you?

Everything Above Board

Doctor: And you say that this has been reviewed by the lens society — you talking about the American Intraocular Implant Society?
Salesman: Right. HCFA.
Doctor: Medicare and Medicaid looked at it?
Salesman: Yeah.
Second Salesman: I'll show you what the question is — draw you a little picture here so that you'll understand. On the invoice, it'll give a description and let's say it's $375. You only can charge back to Medicare and Medicaid the $325 — you can't take the other $50. There isn't any other company in this point in the game that carves that out. What's happening at other companies ... is the patient is financing the equipment, and that's illegal. There isn't any other company today that has gotten all the endorsement we have. And I think one of the reasons that we get it, as said (name omitted) said earlier, our only game that we play is ophthalmology. If we screw it up, we're in trouble, you're in trouble — it's something that I don't think either one of us wants to be a part of.

Medicare Won't Object to Overcharging

Salesman: Medicare's saying to you, Dr. (name omitted), here's your $304 or your $490 or whatever the reimbursement for facility fee — go out and do whatever you can — that's what we're giving you, so go get your best deal — whether that be a program like this or whatever else.
Second Salesman: Well, the other thing is too, even on the intraocular lenses, if you're aware, at least the way it is around here, it may vary from division of Medicare to divison — they don't look at the invoices. They have a set charge — its' a unit pay charge — whatever they allow and I don't recall right now — $480 or $490 — that they allow. They don't say, well, we won't pay as much because you only paid $300 for that lens. They don't look at that.
Salesman: It's not that way. In some parts of the country where I've been, they pay the invoice price plus 10 percent or something — I don't know why they don't do that here. It's different in every county almost ... programs in Ohio (pay) $625. So it is a little confusing how functionally we would show that breakout. What you do is, you take your — let's say it come to three and a quarter — all of a sudden you put $490 customary charge you know, for handling. As long as that's what they're reimbursing at, you wouldn't have any problems. See, actually, because of the reimbursement scheme we have set up for you, this program is even more ideal for you that it is for other parts of the country, because they've already got that price established. And they recognize that as the customary charge on IOLs. So you're in good shape there. But as far as the actual breakdown goes, we go ahead and spell all that out, and it'd be spelled out for you n your invoicing, too. That way Medicare knows exactly what we're doing here.

A Final Seal of Approval

Salesman: The other thing is (name omitted) who is the legal counsel for the society — (name omitted) is also our legal counsel ... So anytime we have any questions of legality, we go directly to (name omitted) on that.
Doctor: That's good to know.

VI. REGULATORY ACTIVITY: ITS ENFORCEMENT, APPROVAL AND REIMBURSEMENT

A. The Food and Drug Administration (FDA)

1. Overview

The Food and Drug Administration is the Federal agency charged with reviewing and approving all intraocular lenses to ensure the safety and efficacy of those IOLs to be implanted. While the Subcommittee found no evidence that FDA's fulfillment of and/or its ability to fulfill this charge has led to the release of potentially harmful lenses, it did find inadequacies and laxaties in FDA authority and activities inviting fraud, waste, and abuse in the testing and marketing IOLs.

Until 1976, the FDA's authority to protect consumers from harmful and unreliable medical devices was severely limited. Existing authority was limited to provisions of the 1938 Federal Food, Drug, and Cosmetic Act authorizing action only if a defect was discovered after a product was in use. There was no requirement for premarket approval of medical devices. Moreover, the FDA had to bear the burden of proving the product was in fact dangerous or fraudulent.

On May 28, 1976, Congress enacted the Medical Device Amendments of 1976 (Public Law 94-295). The law was carefully drawn in an attempt to avoid the adverse effects attributed to the role of drug regulation in the United States. Control was imposed only over the industry, not over the medical community, and specific provisions were incorporated to eliminate delays in certain regulatory considerations.

The law requires that the Department of Health and Human Services provide for the classification of medical devices intended for human use based upon their safety and effectiveness as follows:

(1) Class I includes devices not purported to be for a use which is of substantial importance in supporting, sustaining, or preventing impairment of human life or health, and do not present a potential unreasonable risk or illness or injury, and for which general controls are sufficient;
(2) Class II includes devices for which it is necessary to establish a performance standard to provide reasonable assurances of their safety and effectiveness; and
(3) Class III devices for which there is insufficient information for the establishment of a performance standard to provide reasonable assurances of their safety and effectiveness, are purported to be for a use which is of substantial importance in supporting, sustaining, or preventing impairment of human life or health, or present a potential unreasonable risk of illness or injury.

In addition, the legislation:

- Authorizes the Secretary to establish a performance standard for class II devices.
- Requires premarket approval for class III devices and establishes procedures for such approval.
- Places devices intended for human use, which were not placed in interstate commerce before enactment of the amendments, in class III.
- Authorizes the Secretary to ban devices presenting a substantial deception or a substantial risk of illness or human injury under certain circumstances.
- Authorizes the Secretary to notify all persons necessary under the circumstances to eliminate the risk presented by a particular device.
- Authorizes the Secretary to require a manufacturer of a medical device intended for human use which: (1) presents a substantial risk of harm to the public health, and (2) was not properly designed or manufactured, to repair, replace, or refund the purchase price of such device at no cost to the person using it.
- Requires every person who is a manufacturer, importer, or distributor of medical devices intended for human use to establish and maintain whatever records the Secretary may direct by regulation.
- Authorizes the Secretary to establish mandatory manufacturing methods for medical devices.

- Requires the Secretary to provide for public access to information respecting the safety and effectiveness of devices, including information respecting the adverse effects of the device on health.

- Requires manufacturers of medical devices intended for human use to register with the Secretary.

- Provides for an exception from the requirements of this act, under circumstances determined by the Secretary, to permit the investigational use of medical devices by experts qualified by scientific training and experience to investigate the safety and effectiveness of such devices.

3. IOL Approval Process

Part 813 of Title 21 of the Code of Federal Regulations exempts IOLs from some of the more stringent premarket clearance requirements that other class III devices must meet. In part, this exemption is based on the fact that almost all IOLs are made from same plastic material (PMMA) which has been been adjudged safe and effective for use in the human eye.

The result is that in most instances, all an IOL manufacturer needs to do is file an investigational research protocol with FDA outlining the method to be used to test a particular new lens.

The FDA requires that a manufacturer's investigation produce results of the safety and efficacy of the lens after implantation in at least 500 patients. The data should follow these patients for at least one year and the lenses should be implanted by a qualified investigator (essentially defined as Board Certified Ophthalmologists). This is called a "core" study.

Since these ophthalmologist-investigators are required to document patient progress and produce 6 reports on each patient for manufacturer and FDA use, the FDA does not object to an IOL manufacturer's paying the ophthalmologist for his work as an investigator. The FDA does not regulate the amount paid to investigators.

In addition to the core study, the FDA allows a manufacturer to conduct additional follow-up studies called "adjunct" studies. Adjunct investigators do not routinely have to prepare any reports for FDA use. FDA informed the subcommittee that data maybe available to the manufacturer upon request. FDA also states that FDA does not routinely review this data.

Under this regulatory investigational exemption, manufacturers may arrange for the sale and implantation of the "investigational" IOL by any number of ophthalmologists in any number of patients. The manufacturer may not claim that the IOL is approved or adjudged safe and effective and, at least in theory, all patients receiving the IOL are to to be included in the investigational study. The manufacturer may arrange with any Board Certified Ophthalmologist to be an investigator, and the manufacturer can pay any core or adjunct investigator anything that person wants as compensation for his or her services as an investigator.

5. FDA Backlog and Staffing

The FDA interprets the device legislation to mean that each IOL device produced by each manufacturer, even if identical to another manufacturer approved IOL, must go through the investigational process.

The FDA's Division of Ophthalmic Devices must approve each IOL, contact lens, contact lens saline solution, laser, and surgical device. The Division has a staff of 35 as of May 31, 1985 and has a pending backlog of 606 IOLs in preinvestigational and investigational stages awaiting final approval. As of June 1, 1985, the FDA had approved a total of 76 IOLs. Before the first IOL was finally approved by the FDA, over 500,000 "investigational" IOLs had been implanted in patients' eyes. In April 1985, the FDA has just approved the first IOL in over a year because the staff was diverted to reviewing other ophthalmic devices.

6. Misuse of FDA Approval Process

Subcommittee staff has been made aware of the fact that numerous abuses of the FDA process exist. Several manufacturers have used the IOL investigational process as a way to avoid the anti-kickback and fraud laws. The manufacturers are in effect, paying bribes to ophthalmologists to use a specific lens by calling the bribe a payment for the doctor's services as an investigator. This is especially prevalent in adjunct studies which

really do not place any additional work or reporting burden on the physician. Most manufacturers interviewed by Subcommittee staff acknowledged the existence of this problem and decried the absence of any enforceable industry standards.

FDA has issued warning letters to manufacturers for problems related to investigational implants in large numbers of patients, but no further enforcement action was adjudged necessary by FDA. Despite the abuses of the adjunct investigational process, FDA stated that it "currently has the necessary authority to control adjunct studies."

In May of 1985, the Chairman mailed a questionnaire to the Commissioner of the Food and Drug Administration. The questionnaire focused on the FDA's policies and activities related to the approval of IOLs. The questionnaire and the FDA's response can be found in Appendix C of this report.

B. The Office of the Inspector General

1. Overview

The Office of the Inspector General (OIG) of the Department of Health and Human Services (HHS) was established by Congress in 1976. Congress intended that the OIG be independent of the program operations of the department and that the Inspector General could report only to the Secretary of HHS or to the Congress. This was to assure that the OIG would have the appropriate staffing and flexibility to combat fraud, waste and abuse within the department and the programs (including Medicare) which it administers.

At the request of Chairman Pepper and the Subcommittee, an audit and a preliminary inspection were completed by OIG to review practices in billing and paying for cataract surgery through the Medicare program. The OIG staff reviewed a statistically valid sample of hospital and ophthalmologist bills to Medicare for cataract surgery. Their investigation uncovered program waste and a considerable amount of fraud.

2. Lens Manufacturer Practices

The Inspector General investigation confirmed for the Subcommittee its own evidence of a number of illegal practices involving the sale of intraocular lenses (IOLs). The Inspector General concluded that "the circumstance that gives rise to these ripoffs is the excessive Medicare payments for the lenses." The IG found that the IOL manufacturers were extraordinarily profitable and that much of the illegal activity in can be attributed to some of their overly aggressive salesmen. The Inspector General found that some of the lenses cost as little as $35 to manufacture. A profit of $150 or more is not uncommon on some of these lenses.

3. Provider Charges for IOLs

The OIG review found that provider mark-up for IOLs could even be higher than that of the manufacturers. Lenses that may cost a provider $150-$250 were found to have been charged to Medicare at prices from $300 to over $700. Thus, provider mark-ups ranged from $50 to $550.

As stated earlier, when cataract surgery covered by Medicare is performed on an outpatient basis, the Medicare patient must pay 20 percent of the provider's IOL cost. The OIG investigation uncovered instances where the mark-up was so high that the patient's 20 percent payment was more than the provider's original cost for the lens.

The OIG study did not find any relationship between what Medicare was billed and paid for, and providers' original costs for IOLs.

Charges were even more astonishing when ophthalmologists rather than hospitals were billing Medicare for IOLs. The range of prices paid by doctors were from $0 to $425. The Inspector General found a well known physician who received 1600 free IOLs in exchange for the use of his name in marketing the lense. He billed Medicare $500 for each of these "free" lenses. Last year he made $80,000 profit just on lenses — $65,000 was paid by Medicare and $15,000 by his patients. Including surgical fees, this doctor received over $1.3 million from the Medicare program.

The Inspector General concluded that, "Since the Medicare program is willing to pay 200 percent to 500 percent of the provider's cost for these lenses, it is not surprising that ripoff schemes are prevalent."

Based on a statistically valid sample, OIG found that last year alone, Medicare paid ophthalmologists $6.5 million more that their IOL costs, and beneficiaries paid them an additional $2.8 million. Based on a review of hospital costs and charges, OIG estimates that overall $50 million was wasted by Medicare last year just for IOLs.

4. Excessive Physician Fees

In addition to the problems of IOL costs, the Inspector General's investigation revealed other problems related to cataract surgery paid for by Medicare.

Medicare pays separate bills for cataract surgery to the surgeon, the anesthesiologist, and sometimes an assistant surgeon. The fee Medicare pays for the surgeon's services was determined before the technological changes and advances in skill made cataract surgery less time consuming and complicated. Medicare pays between $960 and $2,000 to the surgeon for an operation usually performed in 30 minutes. Many

ophthalmologists were paid more than $1 million by Medicare in 1984 for cataract surgery. One Florida surgeon performed over 5,000 surgeries in 1984 and received $6.4 million in reimbursement. In the state of Texas alone, six ophthalmologists were paid over $1 million by Medicare in one year.

The OIG study corroborates one of this Subcommittee's most frequent findings: Medicare's reimbursement methods are unable to keep up with technological changes which can substantially lower charges as well as raise them.

In addition, an OIG audit finds little or no justification for Medicare reimbursement for an assistant surgeon in the performance of cataract surgery. These duties are just as competently performed by a nurse or other skilled personnel. The Inspector General estimates that eliminating these payments could save Medicare between $150-$200 million over a five-year period.

Over 90% of cataract surgeries now involve a local anesthetic—frequently administered by the surgeon. Medicare nevertheless pays the same amount ($120-$350) to the anesthesiologist (if one was present during the operation), if he or she used general anesthetic. The Inspector General questions the necessity for Medicare anesthesiologist payment for any but the most complicated cataract surgeries. At the least, Medicare reimbursement should reflect differences in depending whether general or local anesthetic was used and whether the anesthesiologist merely was on "stand-by" for the surgery.

C. Health Care Financing Administration (HCFA)

The Health Care Financing Administration (HCFA) within the Department of Health and Human Services is the Federal agency responsible for the administration and oversight of government reimbursement for cataract surgery through the Medicare program. The Subcommittee found serious inadequacies in HCFA's oversight and policy in this area resulting in the waste of over $1.2 billion in Medicare funds.

The Medicare program, which began on July 1, 1966, was authorized by the Social Security Amendments of 1965, which added Title XVIII of the Social Security Act. Medicare pays for much of the health care costs for eligible persons aged 65 or older. The program is administered by the Health Care Financing Administration (HCFA), a component of the Department of Health and Human Services (HHS).

HCFA administers Medicare through a network of contractors, such as Blue Cross and Blue Shield, to process Medicare claims and to make payments on behalf of the government. The contractors that pay institutional providers, such as hospitals and nursing homes, are referred to as part A intermediaries; the contractors that pay for the services of noninstitutional providers, such as doctors, laboratories, and suppliers, are called part B carriers.

In fiscal year 1984, Medicare paid about $42 billion to the approximately 6,000 hospitals that participate in the program. We estimate that expenditures for inpatient and outpatient services for cataract surgery under Medicare in fiscal year 1985 will amount to about $3.5 billion.

From Medicare's initiation on July 1, 1966, until fiscal year 1984, the program paid hospitals, on a retrospective basis, their reasonable costs of providing covered services to beneficiaries. Although the reasonable cost methodology included provisions designed to control Medicare cost growth, there was a general concern that this payment system did not give hospitals sufficient incentives to provide care economically and efficiently. As a result of this concern, the Congress enacted as part of the Social Security Amendments of 1983 (Public Law 98-21) a hospital prospective payment system for Medicare. Under the new system, the amount a hospital will be paid is determined before the period in which the payments are made, and normally payments are not adjusted retrospectively to reflect actual costs. The payment rate depends on into which diagnosis related group (DRG) the case is classified. The prospective payment system is being phased in over 3 years beginning in fiscal year 1984, and eventually hospitals will be paid a uniform rate (adjusted to reflect variations in local wage levels, urban or rural location, and teaching status) established for each DRG.

Each DRG contains diagnoses which are expected to be closely related in the extent of resources devoted to treating patients. DRG 39, Lens Procedures, which includes the removal of cataracts, resulted in over 395,000 discharges during fiscal year 1984. In addition, DRG 42, Intraocular Procedures except Retina, Iris and Lens, which was intended to cover complications of cataract and other eye operations, resulted in almost 35,000 discharges. HCFA was unable to provide us with accurate data on the number of non-DRG inpatient cataract operation performed in 1984.

The Social Security Amendments of 1983 also strengthened the role of utilization and quality control Peer Review Organizations (PROs), which are usually statewide bodies of medical professionals under contract with HCFA to review the medical necessity and appropriateness of health care services provided under Medicare. The amendments require hospitals, as a condition of receiving Medicare payments, to enter into a contract with the PRO covering their area, to review such factors as quality of care and utilization of services. The legislation also specifies that PROs will review the validity of diagnostic information provided by hospitals and the appropriateness of admissions and discharges. HCFA required most PROs to review every inpatient cataract surgery procedure and to deny payment for all that are unnecessary. The primary focus of the PROs however is to ensure that no cataract surgery be performed inpatient if it can be performed outpatient instead. The assumption behind this policy is that outpatient surgery is less expensive, and less traumatic for the patient.

Despite the fact that HCFA is rapidly forcing most cataract surgery from inpatient to outpatient, we have been informed that "Data on procedures for outpatient hospital services are not collected." No data was provided for other outpatient locales.

Hence, HCFA in effect has no practical way to evaluate the effectiveness (or ineffectiveness) of the policy they are implementing.

As discussed in Section I B(1) of this report, HCFA has no uniform policy requiring its carriers and intermediaries to cap reimbursement for IOLs. This allows for great

variations found by the Subcommittee in rates from $290-$665 paid by Medicare for essentially identical lenses.

In May of 1985, the Chairman mailed a questionnaire to the Administrator of the Health Care Financing Administration. In his request for information, the Chairman posed a series of questions relating to HCFA's policies and activities surrounding Medicare payments associated with cataract surgery. The questionnaire and HCFA's response can be found in Appendix D of this report.

VII. POLICY RECOMMENDATIONS

It is apparent that cataract surgery represents the best and worst of modern medicine. The Subcommittee is impressed with the technological advances made in the last five years. Cataract surgery is now faster, less painful and more effective. For literally millions of senior citizens these improvements have provided the precious gift of better vision.

From the taxpayers' perspective, however, cataract surgery is an unmitigated disaster. With almost 50 percent of all the money spent on cataract surgery drained away by fraud, waste and abuse, Americans are losing up to $2 billion annually. If nothing is done, upwards of $12 billion, $10 billion by the Medicare program alone, will be lost by the end of this decade.

At a moment in time when Congress is struggling to find ways to reduce the soaring Federal deficit, often by making difficult and painful program reductions, we cannot in good conscience ignore this grand scale squandering surrounding cataract surgery.

With some improvements in program administration and legislative changes, we could continue to provide necessary and effective cataract surgery, enjoy its rich benefits, but without the fraud, waste and abuse. During the course of its investigation the Subcommitee has developed a series of recommendations — to the Congress, Federal agencies, senior citizen consumers and others — aimed at providing these much needed improvements.

- Congress should consider legislation which would limit Medicare payments for cataract surgery performed in a hospital outpatient or ambulatory surgical center setting to some percent less than that paid for the same in a hospital inpatient setting. Information on cost savings, program effectiveness and patient well-being derived from this change could serve as a basis for adopting this policy for all surgical procedures performed in different settings.

- Congress should consider legislation eliminating Medicare payments for asssistant surgeons for all outpatient surgery unless preapproved by the PRO or Medicare carrier.

- Congress should consider legislation requiring HCFA to set strict policy and reimbursement limits on anethesiologist bills— paying only for general anesthesia anod only if preapproved. Medicare should only pay a nominal amount if an anesthesiologist is only on "stand by".

- Congress should consider legislation requiring Medicare to pay cost and not charges for all prosthetic devices.

- Congress should consider legislation giving FDA authority to regulate amounts paid by manufacturers to investigators of all types of investigational devices.

- Congress should consider legislation to require the Congressional Office of Technology Assessment (OTA) to conduct an annual review of changes in technology and skill involving artificial devices and organs and their implantation and to advise the Secretary of DHHS to reflect changes in Medicare charges.

- One distressing finding of the Subcommittee is that from 23%-36% of all cataract surgery may be unnecessary. Instances of senior citizens with perfect 20/20 vision being operated on were reported. We therefore strongly recommend that anyone needing cataract surgery seek the opinion of at least one other qualified doctor before undergoing surgery. Unnecessary surgery is not only wasteful but can adversely impact on the patient's health and well-being.

Health Care Financing Administration (HCFA)

The Subcommittee is dismayed that HCFA is busy implementing a policy of forcing all cataract surgery from inpatient to outpatient basis, without collecting any data to allow it to evaluate how this policy is working. We are distressed that HCFA has not made any effective effort to control the excessive charges made by hospital outpatient departments, or for unnecessary professional services in all surgical procedures.

- HCFA should immediately begin to collect and analyze data on all outpatient

surgeries reimbursed for by Medicare to determine their costs and effectiveness.

— HCFA should immediately implement and enforce a uniform policy for its carriers on payments for IOLs.

Food and Drug Administration

The Subcommittee is distressed that FDA has allowed the continuation of adjunct studies of IOLs. We see these studies as wasteful and of little if any use. FDA does not use the data collected from these studies. Many of these studies are required of IOLs which are identical to those already approved for use.

The Subcommittee is also distressed that FDA has scant little control over who conducts investigations of nonapproved devices, what these investigators are paid by the manufacturers of these devices, and the extent of commercialization of nonapproved devices.

— The FDA should immediately take steps to eliminate adjunct studies for IOLs.

— The FDA should take steps to reduce its backlog of devices awaiting approval.

U.S. Department of Justice

The Department of Justice should actively seek out and prosecute cases of fraud and abuse involving cataract surgery and the sale of IOLs.

Ophthalmology Profession

The professional associations should formally censure the types of improper and illegal sales inducements outlined in this report.

VIII. CONCLUSION

The Subcommittee found that cataract surgery — the most frequently reimbursed major surgical procedure under the Medicare program — is fraught with fraud, waste and abuse. As this report has shown, there is reason to question the necessity or validity of half of the dollars that Medicare pays for cataract surgery — as much as $2 billion of the $3.5 billion we pay for this miraculous procedure is drained away inappropriately.

At a moment in time when Congress is struggling to find ways to reduce the soaring Federal deficit and retain important income and health benefits for senior citizens, often by making difficult and painful program reductions, we cannot in good conscience ignore this grand scale squandering surrounding cataract surgery.

With some improvements in program administration and legislative changes, we could continue to provide necessary and effective cataract surgery, enjoy its rich benefits, but without the fraud, waste and abuse.

It is our hope that this report will lead to much needed reform and that the millions of Americans who will be seeking this surgery will get the most appropriate and affordable care available.

IX. GLOSSARY OF TERMS SPECIFIC TO THE CATARACT INDUSTRY AND AN ANATOMY OF THE EYE

Glossary of Terms:

aphakia: the absence of the natural lens of the eye, most commonly the result of cataract surgery.

ASC or Ambulatory Surgical Centers: operating rooms located outside of hospitals in which outpatient surgery is performed.

cataract: a cloudy or opaque area in part or all of the transparent lens located inside the eye.

cryoextraction: an intraocular extraction technique by which a cataract is frozen and removed using a very cold probe.

DRG or Diagnostic Related Group: one of 468 categories for disease and disorders upon which Medicare part A bases its reimbursement schedules.

extracapsular extraction: method of cataract removal in which the clouded lens is removed along with the front portion of the lens capusle, while the rear portion of the capsule is left behind.

Healon (Sodium Hyaluronate): a thick, gel-like, man-made material injected into the eye to maintain its shape during surgery.

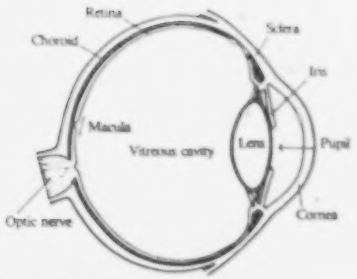
intracapsular extraction: method of cataract removal in which the entire lens capsule is removed along with the clouded lens.

IOL or intraocular lens: a synthetic lens inplanted in the eye used to replace the natural crystalline lens.

prosthetic lenses: lenses which work in conjunction with or replace the natural lens of the eye, including glasses, contact lenses, and IOLs.

vitreous humor: a very thick, gel-like natural material found in the eye that serves to maintain the spherica shape of the eye.

An Anatomy of the Eye



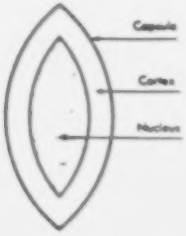
Cornea: the clear membrane covering the exterior surface of the eye. It is reponsible for focusing the light rays on the retina, and is misshapen in conditions such as astigmatism, nearsightedness,and farsightedness. These conditions are usually corrected by glasses or contact lenses.

Iris: the colored portion of the eye which forms a ring around the pupil.

Pupil: the aperature which permits light to enter the eye. The diameter is varied to alter the amount of light permitted to enter depending on the brightness of the environment.

Sclera: the white of the eye.

Lens: the lens functions to allow the eye to change its focus between near and far objects.



crystalline lens

Vitreous cavity: the large chamber behind the lens, filled with vitreous humor, a very thick gel-like fluid which maintains the shape of the hollow eye.

Retina: sensory sight of the eye where light input is transformed into electrical neural input so that it can be interpreted by the brain.

Macula: the area of the retina containing the highest density of rods and cones, the specialized cells which transform light into neural information. The macula is reponsible for fine discriminative vision.

Choroid: the portion of the eye containing the blood vessels which supply the retina.

Optic nerve: the nerve which transmits the visual input from the eye to the brain.

APPENDICES

APPENDIX A

OPHTHALMOLOGIST QUESTIONNAIRE

NAME: _____

ADDRESS: _____

_____

_____

_____

TELEPHONE: _____

1a. How many patients did you see/treat in 1984?____ In 1983?____

1b. What percentage of your patients are over the age of 65?____%

2a. With which intraocular lens manufacturer do you do business?

_____

2b. Are you an investigator for this manufacturer?____YES ____NO

3. Are you aware of any of the following types of purchasing arrangements which may be employed by intraocular lens manufacturers/sales representatives?

		YES	NO
a.	Awards of vacations to physicians for purchasing a certain number of intraocular lenses	___	___
b.	Discounts to physicians for volume purchases of intraocular lenses	___	___
c.	Gifts of stock in your company to physicians who purchase a certain number of lenses	___	___
d.	Cash rebates to physicians who purchase from your company	___	___
e.	Free intraocular lenses provided to physicians after they have purchased a certain number from your company	___	___
f.	Progressive discounts for repeat volume orders	___	___
g.	Other (please specify) _____		

Please describe any other purchase arrangements you are aware of. Also, please use this space to elaborate on any "Yes" answers above.

4a. Are these arrangements being offered by the manufacturers or manufacturer salesmen with whom you do business? ____YES ____NO

4b. To your knowledge, are these arrangements being offered by other manufacturers? ____YES ____NO If yes, by whom?

5. Do you consider these arrangements to be kickbacks, bribes or other improper inducements?____YES ____NO Elaborate, if necessary.

6. Have you ever declined to participate in a purchase arrangement similar to those described above, or others?____YES ____NO If yes, why?

7. If you participate in a purchase arrangement which provides a financial incentive or benefit for dealing with a particular company, do you pass along the savings to your patients and any affected third party payor? _____YES _____NO If yes, please explain how you pass these savings along to the Medicare program or beneficiary/patient.

7a. How much financial benefit is derived from this plan? _____

8. Do you feel that intraocular lens manufacturers/sales representatives should be free to offer incentives to physicians to purchase a particular brands of lens?
____Yes ____No Why? _____

9. Would you be willing to testify before this Subcommittee on your experience and/or knowledge of intraocular lens purchase arrangements? ____Yes ____No

11. Please feel free to share any additional thoughts you may have on attached sheets or call us at (202) 226-3381 with this information.

PLEASE RETURN COMPLETED QUESTIONNAIRE TO:

SUBCOMMITTEE ON HEALTH AND LONG-TERM CARE
Select Committee on Aging
HI-377
U.S. House of Representatives
Washington, DC 20515

Thank you in advance for your prompt response.

APPENDIX B

INDUSTRY QUESTIONNAIRE
(Please attach additional sheets if needed)

Name of Firm:
Address:

Contact Person:
Telephone:

1. In how many states do you operate? _____

2. What were you total assets in 1983? _____ In 1984? _____

3. What were your total gross revenues from sale of intraocular lenses for 1983?_____ 1984?_____

   Could you please furnish us a copy of your most recent annual report?

4. How many people does your company employ?_____ How many are involved in marketing your intraocular lenses?_____ Of these, how many are sales representatives?_____ How many are administrative?_____ Other? provide a distribution by sale.

5. Are your sales representatives your employees or are they independent contractors? Employees___% Independent Contractors___% Others (specify) ___%

6. Do you provide company training relative to intraocular lens sales to your sales representatives? ___YES ___NO. If yes, could you please provide me with a copy of your training manual.

   Is it mandatory to undertake this training before selling your lenses?
   ___YES ___NO If not, why not?

7. Do your sales representatives work on a salary basis ____%, commission basis %, or combination of the two? ___%

8. What is the average yearly income (excluding benefits) for your intraocular lens sales representatives? _____

9. Are you aware of intraocular lenses being marketed under any of the following sales plans?

	YES	NO
a. Awards of vacations to physicians for purchasing a certain number of intraocular lenses		
b. Discounts to physicians for volume purchases of intraocular lenses		
c. Gifts of stock in your company to physicians who purchase a certain number of lenses		
d. Cash rebates to physicians who purchase from your company		
e. Free intraocular lenses provided to physicians after they have purchased a certain number from your company		
f. Increasingly greater discounts to physicians who make repeated volume orders.		
g. Other (specify)		

Please attach sheet to elaborate on any "Yes" answers above.

10. Have you or your sales representatives ever employed these techniques? Please describe any other marketing plans your company employes. Also, please use this space to elaborate on any "Yes" answers.

Are these company plans or are they employed on an optional basis by individual sales representatives? If so, which ones?

11. If your company does not employ any marketing plans similar to those above, are you, nevertheless, aware of any companies which utilize such plans?
___YES ___NO
Please identify the companies and/or nature of their marketing plans.

12. What is the purpose of employing these marketing techniques?

13. If your company employs a marketing plan which offers a financial incentive or benefit to participating physicians, do you advise them to pass along their benefit in terms of cost savings to the patients and third party payors?____Yes _____No

If not, why not?

If yes, how do physicians pass along savings under your plan?

14. Have your representatives ever been approached by physicians asking for special considerations, money or other inducements for using your lens?____Yes ____No
If so, please explain.

15. How would you characterize the nature of the industry?____Competitive
____Non-Competitive ____Very competitive

16. Would you be willing to testify before this Subcommittee on the marketing of intraocular lenses? _____Yes _____No

17. Please feel free to share any additional comments you may have on attached sheets, or call us at (202) 226-3381 with this information. Thank you for responding.

PLEASE RETURN COMPLETED QUESTIONNAIRE TO:
Subcommittee on Health and Long-Term Care
House Select Committee on Aging
H2-377
U.S. House of Representatives
Washington, DC 20515

APPENDIX C

U.S. House of Representatives
SELECT COMMITTEE ON AGING
SUBCOMMITTEE ON HEALTH AND LONG-TERM CARE
Washington, DC 20515

May 22, 1985

Dear Dr. Young:

The Subcommittee on Health and Long-Term Care of the House Select Committee on Aging is investigating a number of issues involving cataract surgery. To this end, we would very much appreciate your agency providing us with the following information:

- How many intraocular lenses (IOL's) have received final FDA approval?
- How many IOL's are approved for core investigational study?
- How many IOL's are approved for adjunct studies?
- How many IOL's are awaiting approval to begin investigational studies?
- What is the current staffing of the Division of Opthalmic Devices and what is the overall pending workload?
- What specific steps has FDA taken to prohibit overcommercialization of univestigated IOL's?
- Has FDA investigated or taken any compliance actions against any IOL manufacturers? To what use does FDA put adjunct studies? Should FDA's authority to control adjunct studies be changed in any manner?
- FDA's authority to regulate devices is almost ten years old. In light of your experience in this area, are there some legislative or regulatory mandates which should be changed either to simplify procedures or to strengthen regulatory authority?

We would like to ask that we receive this important information by June 3, 1985. If you or your staff has any questions regarding this request, please contact the Subcommittee Staff Director, Kathleen Gardner Cravedi, at (202)226-3201.

Kindest regards, and,

Very sincerely,

Claude Pepper
Chairman

Frank E. Young, M.D., Ph.D.
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

CPepr

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

The Honorable Claude Pepper
Chairman, Subcommittee on Health
and Long-Term Care
Select Committee on Aging
House of Representatives
Washington, D.C. 20515

JUL 0 9 1985

Dear Mr. Pepper:

I write to reply to your letter dated May 22, 1985 regarding the Food and Drug Administration's intraocular lens (IOL) activities. I am pleased to submit the enclosed information which details the Agency's activities, both in terms of processing applications for new investigational products as well as enforcement of the present rules and statutory requirements.

Enclosed is material responsive to your questions on the Agency's IOL program. I will be happy to provide any additional information you may want on this important issue.

Sincerely yours,

Frank E. Young, M.D., Ph.D.
Commissioner of Food and Drugs

Enclosure

RESPONSE TO MR. PEPPER'S REQUEST FOR INFORMATION ON INTRAOCULAR LENSES

Responses to questions raised in Mr. Pepper's letter are provided in the order in which the questions appeared in the May 22, 1985, letter. The intraocular lens (IOL) utilization data provided in items 1 through 4 are based upon data obtained from a telephone survey conducted during the week of May 30 through June 3, 1985, of 18 IOL manufacturers that are operating under approved investigational device exemption (IDE) applications. Although FDA has not verified the accuracy of each and every number provided by the manufacturers, we have no reason to doubt their accuracy.

1. Question: How many IOLs have received final FDA approval?

   Response: As of May 31, 1985, premarket approval applications (PMAs) had been approved for 7 different manufacturers to market 76 different IOL models. These 76 models include 59 posterior chamber IOLs by 6 different manufacturers, 11 anterior chamber IOLs by 4 manufacturers, 4 iridocapsular IOL models by 2 manufacturers, and 2 iris fixation IOL models by 1 manufacturer.

   During the period of January 1, 1984, through December 31, 1984 (in some instances February 1, 1984, through January 31, 1985), approximately 103,043 PMA approved IOLs were implanted.

2. Question: How many IOLs are approved for core investigational studies?

   Response: As of May 31, 1985, 313 different IOL models had been approved for core investigational studies for 16 different manufacturers. During the period identified in the second paragraph of the response to item 1, approximately 23,497 core investigational lenses were implanted. The models include 164 IOL models made of standard polymethylmethacrylate (PMMA), 135 models made of PMMA plus UV-absorbing materials, and 14 models made of soft materials.

3. Question: How many IOLs are approved for adjunct studies?

   Response: As of May 31, 1985, 531 different IOL models had been approved for adjunct studies by 17 manufacturers. During the period identified in items 1 and 2, approximately 714,286 adjunct investigational IOLs were implanted. The models included 346 models made of standard PMMA and 185 models made of PMMA plus UV-absorbing materials.

4. Question: How many IOLs are awaiting approval to begin investigational studies?

   Response: As of May 31, 1985, 52 different IOL models are awaiting approval to begin investigational studies (i.e., the IDE applications have been at FDA for fewer than 30 days). These models include 7 IOLs made of standard PMMA, 44 IOLs made of PMMA plus UV-absorbing materials and 1 IOL made of soft material.

5. Question: What is the current staffing of the Division of Ophthalmic Devices (DOD), and what is the overall pending workload?

Response: DOD is the largest of seven divisions in FDA's Center for Devices and Radiological Health (CDRH) Office of Device Evaluation (ODE), with 35 full-time equivalents (FTEs) currently on board. Twenty-five percent of ODE's scientific review personnel are allocated to DOD. To compensate for growing workloads, staffing of DOD has been increased by 5.5 FTEs since the beginning of Fiscal Year (FY) 1985, despite a reduction in overall resources in FDA's CDRH.

DOD has three branches: the Intraocular Lens Branch, the Contact Lens Branch, and the Surgical and Diagnostic Devices Branch.

During the first half of FY 1985, the incoming workload of DOD was as follows:

Type of Submission	No. Received by DOD	DOD's Share of Total ODE Submissions
Premarket Notifications (510(k)s)	98	4%
IDE Applications	26	28%
IDE Supplements	463	36%
PMAs	23	52%
PMA Supplements	89	45%
Total	699	17%

*DOD's share of total ODE workload (number of incoming submissions weighted by resource-intensiveness) equals 27%.

Currently, the following numbers of submissions are under active review in DOD:

Type of Submission	No. Under Review	DOD's Average Response Time (Days) Per Submission, First Half FY '85
Premarket Notifications (510(k)s)	26	94
IDE Applications	9	55
IDE Supplements	750	34
PMAs	42	356*
PMA Supplements	228	287*

*PMA review times are for "initial" decision -- the first decision on the approvability of the application after it has been accepted for filing -- excluding time for manufacturer's responses to scientific deficiency letters.

6. Question: What specific steps has FDA taken to prohibit over-commercialization of uninvestigated IOLs?

Response: We are not certain what you mean by uninvestigated IOLs. Therefore, we are directing our response to the steps which FDA has taken to prevent the commercialization of investigational IOLs and those IOLs that FDA has not approved.

The IDE regulation for IOLs (21 CFR Part 813) allows sponsors to charge for an IOL, provided the sponsor, in the IDE application, notifies FDA that there will be a charge to investigators and subjects for the device (813.20(b)(15)). No further information regarding charges is generally submitted or requested.

Other steps that FDA has taken to limit the commercialization of investigational IOLs include limits on the promotional practices and advertising by sponsors and investigators. Regulation 21 CFR 813.50 prohibits the sponsor or any person acting for or on behalf of the sponsor to disseminate any promotional material that represents that the lens being investigated is safe and effective for the purposes for which it is being investigated. Such claims are also prohibited in advertising and in the representations made at trade shows or professional conferences. Such claims would provide cause for withdrawal of approval of IDE or other regulatory action. FDA has developed a "Guideline for Reviewing Notices of Availability for Intraocular Lenses" (enclosure 1) which has been widely distributed throughout the IOL industry. This guideline outlines information that would be acceptable to FDA in notices of availability of IOLs.

Please refer to enclosure 2 in reply to Question 7a (section 813.50, pages 4-5) for a summary of actions taken by FDA against firms that promoted the use of their IOLs during their investigation.

7a. Question: Has FDA investigated or taken any compliance actions against any IOL manufacturers?

Response: FDA's regulatory actions regarding IOL investigations are summarized in enclosure 2. These actions were based on violations of the IOL regulation (21 CFR 813) and on reviews of IDE applications submitted in accordance with the IOL regulation.

7b. Question: To what use does FDA put adjunct studies?

Response: FDA requires that data from these studies be available to the sponsor upon request.

Adjunct visual acuity and complication rate data have been used to confirm core data although these data are not routinely reviewed in PMAs.

Under section 813.153 of FDA's regulations, if during an investigation a serious adverse reaction occurs that may reasonably be regarded as lens related and that was not anticipated in nature, severity, or degree of incidence in the investigational plan (adverse reactions include any incidence of hypopyon, intraocular infection, acute corneal decompensation--or any secondary surgical intervention), the investigator must investigate the reaction and submit an accurate and adequate report of the investigation to the sponsor within 5 days. The sponsor in turn must report the adverse reaction and results to FDA within 5 days. All adverse reactions (core and adjunct) are analyzed by the sponsor and FDA for PMA approval purposes.

7c. Question: Should FDA's authority to control adjunct studies be changed in any manner?

Response: No. FDA currently has the necessary authority to control adjunct studies. The Investigational Device Exemption Criticism Task Force recently considered this question and concluded that additional authority to control adjunct studies is not necessary. How adjunct studies (which are not specifically mentioned in 21 CFR, Part 813) are controlled is a matter of FDA policy and interpretation of the regulations.

As you know, when FDA initially began regulating IOLs under the Medical Device Amendments of 1976, while Congress was considering these Amendments, some ophthalmologists expressed concern that the new law would unduly inhibit the development of IOLs; IOLs were on the market at that time. Therefore, Congress directed FDA to ensure that IOLs continue to be made "reasonably available" to qualified investigators to implant while data were being collected that would enable FDA to decide whether IOLs should be approved for general marketing. The adjunct study was designed to fulfill that purpose and to collect data on infrequently-occurring complications.

At this time FDA believes that because a large number of IOL models have been granted PMA approval and PMA approval is imminent for several other models, the Congressional mandate of assuring that IOLs be made "reasonably available" has been met. For this reason, FDA is reexamining its policy of allowing sponsors to include adjunct study patients in their investigational protocols. FDA is developing a policy on (a) whether investigations of new IOLs should be restricted to core patients; (b) whether and how additional patients may be entered after submission of a PMA to FDA; and (c) what should be done about ongoing investigations that include adjunct studies.

8. Question: FDA's authority to regulate devices is almost ten years old. In light of your experience in this area, are there some legislative or regulatory mandates which should be changed either to simplify procedures or to strengthen regulatory authority?

Response: On April 23, 1985 Secretary Heckler submitted to Congress a legislative proposal that would simplify the medical device standard-setting process (i.e., streamlining the current five-step process into a two-step process) and would provide discretionary authority for the initiation of such standards. That proposal has been introduced as H.R. 2177.

In addition, FDA has recently undertaken an intensive review of the Medical Device Program. This review resulted in the establishment of 11 task forces to review the following areas: civil penalties, device definition, education, good manufacturing practices, investigational device exemption, premarket approval, preamendment PMA, premarket notification, reclassification, 518(b) and the effect of the Medical Device Amendments on small business.

These task forces have completed their deliberations and are in the process of finalizing reports that may contain recommendations for changes in management processes, policy, regulations, and the statute.

Enclosure 1

GUIDELINE FOR REVIEWING NOTICES OF AVAILABILITY FOR INTRAOCULAR LENSES

a. be limited to information needed to adequately inform physicians of their availability for investigational use;

b. be placed only in medical or scientific publications whose readership is composed of physicians or institutions providing ophthalmological services;

c. not include claims, either overt or implied, that the lenses are safe or effective for the purposes under investigation;

d. include only objective statements concerning the physical nature of the lenses; i.e., size, power, composition, etc.;

e. not include comparative pictorial descriptions, but may include reasonably sized drawings or photographs of the lenses;

f. include the following statements, prominently displayed in type consistent with other type in the notice;

"Caution - investigational device. Limited by Federal (or United States) law to investigational use."

g. include the name and address of the sponsor and may include statements describing how they can be obtained.

In the future our staff will use the above for guidance when reviewing material for possible violations of 21 CFR 813.50.

Division of Compliance Operations
May 1981

Enclosure 2

INTRAOCULAR LENSES (IOLs)

Section 813.25(a):

1. On 11/2/82, Precision Cosmet was issued a letter regarding the high rate of macular edema with the lenses implanted. No further regulatory action was necessary since appropriate steps were taken by the sponsor to correct the problem.

2. On 6/8/81, Precision Cosmet was issued a letter regarding the carcinogenic effects of the blue suture material and requested further study. No further regulatory action was necessary since the sponsor resolved the issue.

3. On 11/14/79, Precision Cosmet was issued a letter regarding the incidence of adverse effects in anterior chamber lenses and that further addition of investigators will be denied. No further regulatory action was necessary since the sponsor resolved the issue.

4. On 5/27/83, Copeland Intra Lenses was issued a letter regarding the safety issues associated with the ICCE implantation portion of the protocol. No further regulatory action was necessary since the sponsor voluntarily terminated that portion of the investigation.

5. On 9/9/82, Intermedics was issued a letter regarding the incidence of adverse effects with the iris plane lenses. No further regulatory action was necessary since the sponsor voluntarily ceased further implantation.

6. On 9/16/83, Intermedics was issued a letter regarding the high rate of adverse effects. No further regulatory action was necessary since the sponsor resolved the issue.

7. On 11/1/82, Surgidev was issued a letter regarding the high rate of adverse effects. No further regulatory action was necessary since the sponsor resolved the issue.

8. On 7/14/83, Medical Workshops was issued a letter regarding the problem of low visual acuity with the Medallion IOLs. No further regulatory action was necessary since the sponsor resolved the issue.

9. On 9/14/81, Medical Workshops was issued a letter regarding the incidence of adverse effects. No further regulatory action was necessary since the sponsor resolved the issue.

Section 813.39(b):

1. On 7/12/78, Coburn Optical Industries was issued a letter regarding the failure to submit a supplemental application for EtO sterilization. No further regulatory action was necessary since the sponsor obtained FDA approval.

2. On 1/13/84, Intermedics was issued a letter regarding the distribution of various lenses without obtaining approval through a supplemental application. No further regulatory action was necessary since approval was obtained.

3. On 8/11/82, Surgidev was issued a letter regarding their failure to submit a supplemental application for new lens styles. No further regulatory action since the sponsor obtained approval.

4. On 12/7/79, Copeland and CILCO were issued notice of adverse findings letters regarding: (1) a clinical investigator implanting lenses under both sponsors' investigations prior to obtaining FDA and IRB approvals; and (2) deficiencies in the informed consent documents. Both sponsors brought the investigator into compliance, obtained approvals and revised the consent document; no further regulatory action was necessary.

5. On 1/17/83, IOPTEX was issued a letter regarding the expansion of the trial study from 150 patients to 950 patients without obtaining FDA approval. FDA required the sponsor to: (1) cease further shipments; (2) notify all investigators to cease implantation; (3) submit specific data within 30 days; and (4) submit data on other lens studies within 30 days. The sponsor met the requirements of this letter and no further implants were permitted. No further regulatory action was necessary.

6. On 8/11/82, Surgidev was issued a letter regarding changes made in two lens styles without submitting a supplemental application and obtaining FDA approval. The sponsor submitted the supplemental application and obtained approval. However, restrictions were placed on the number of lenses to be implanted; no further regulatory action was necessary.

7. On 5/31/79, McGhan was issued a notice of adverse findings letter regarding shipping lenses to an unapproved investigator. The sponsor obtained approval for the investigator; no further regulatory action was necessary.

Section 813.46:

1. On 6/20/78, Precision Cosmet was issued a letter regarding inadequate monitoring and lack of documenting informed consent. No further regulatory action was necessary since the sponsor resolved the issues.

2. On 9/22/80, Intermedics was issued a letter regarding a traveling investigator who implanted 1639 lenses nationwide and had a 78% lost-to-follow-up rate. The sponsor was required to limit the investigation to investigators who would closely follow all patients. No further regulatory action was necessary since the investigator was not permitted to implant and previous subjects were followed by other investigators.

3. On 5/11/82, Precision Cosmet was issued a letter regarding an investigator who implanted IOLs and had subjects from around the country. The subjects were subsequently lost-to-follow-up. The sponsor was required to assure follow-up of all subjects enrolled in the investigation. No further regulatory action was necessary since the subjects were followed by other investigators.

4. On 2/6/79, Coburn was issued a notice of adverse findings letter regarding deficiencies in records required to be kept by the sponsor, i.e., no post-operative exam records, and shipment of lenses without approval. The sponsor made the corrections in record deficiencies and ceased shipment of unapproved lenses; no further regulatory action was necessary.

5. On 2/9/79, IOLAB was issued a notice of adverse findings letter regarding unaccountable shipment records and labeling deficiencies, i.e., sterilization shelf-life discrepancies. The sponsor corrected the shipment records and revised the labeling; no further regulatory action was necessary.

6. On 2/12/79, Copeland was issued a notice of adverse findings letter regarding an investigator's missing patient records and not maintaining the required records. The sponsor brought the investigator into compliance with the recordkeeping requirements; no further regulatory action was necessary.

7. On 3/30/79, Surgidev was issued a notice of adverse findings letter regarding an investigator's inconsistent recordkeeping and control over the lenses. The sponsor brought the investigator into compliance with their responsibilities; no further regulatory action was necessary.

8. On 5/31/79, Medicornea was issued a notice of adverse finding letter regarding deficiencies in their recordkeeping and deficiencies in an investigator's recordkeeping and lack of reports. The sponsor corrected their records and brought the investigator into compliance; no further regulatory action was necessary.

9. On 6/11/79, Medical Workshop was issued a notice of adverse findings letter regarding discrepancies in subject records and lack of quarantine of defective lenses from lenses waiting for shipment. The sponsor corrected their records and isolated the necessary lenses; no further regulatory action was necessary.

10. On 7/15/81, Medical Workshop was issued a letter regarding the high adverse reaction of hypopyon. The sponsor issued a recall of all remaining lenses and terminated the investigation.

Section 813.50:

1. On 5/25/83, Precision Cosmet was issued a letter regarding promotional language in the device labeling. No further regulatory action was necessary since the sponsor corrected the labeling.

2. On 11/29/82, Americal International was issued a letter regarding misleading labeling, i.e., sizing of lenses and unapproved safety claims. The sponsor revised the labeling; no further regulatory action was necessary.

3. On 5/23/83, Copeland was issued a letter regarding misleading labeling, i.e., misuse of the term "UV" and sizing of lenses. The sponsor revised the labeling; no further regulatory action was necessary.

4. On 7/18/83, CILCO was issued a letter regarding labeling deficiencies, i.e., safety claims, inappropriate caution statement, and reference to "FDA approved" products. The sponsor corrected the labeling; no further regulatory action was necessary.

5. On 9/29/83, Optical Radiation Corporation was issued a letter regarding inaccurate lens sizing information in the labeling. The sponsor revised the labeling; no further regulatory action was necessary.

6. On 12/2/83, Lynell was issued a letter regarding inappropriate placement of caution statement in the device labeling. The sponsor revised the labeling; no further regulatory action was necessary.

7. On 9/27/83, Precision Cosmet was issued a letter regarding distribution of promotional material on the investigational lens at professional meetings. The sponsor revised the literature to delete all promotional statements; no further regulatory action was necessary.

8. On 9/30/83, CILCO was issued a letter regarding distribution of promotional material on the investigational lens at professional meetings. The sponsor revised the literature to delete all promotional statements; no further regulatory action was necessary.

9. On 5/22/83, Intermedics was issued a letter regarding distribution of promotional information on the investigational lens. The sponsor revised the literature; no further regulatory action was necessary.

10. On 12/24/80, 12 manufacturers of IOLs were issued letters concerning advertisements in professional journals and FDA's interpretation of the regulation.

11. On 2/3/83, Surgidev, Corp. was issued a letter regarding the promotion and advertising of a lens before PMA approval. No further action was taken.

12. On 9/30/83, CILCO was issued a letter regarding an exhibit at a professional meeting at which brochures were distributed alluding to safety and effectiveness of a lens. The firm agreed to halt further distribution and no futher action was taken.

Section 813.65:

On 2/1/80, Coburn Optical Industries was issued a letter regarding review and approval of their investigation by an IRB not conforming to the required review procedure. No further regulatory action was necessary since the sponsor resolved the issue with the IRB.

Section 813.2:

1. On 6/28/78, IOLAB was issued a letter regarding the determination that the model [redacted] is not a custom device and is subject to Section 813. No further regulatory action was necessary since the sponsor resolved the issue.

2. On 4/25/78, Intermedics was issued a letter regarding the need to comply with the IOL regulation, effective February 9, 1978. No further regulatory action was necessary since the sponsor brought the investigation into compliance with Section 813.

Section 813.150:

On 4/27/79, the [redacted] was issued a letter regarding the laboratory's refusal to permit inspection, and that any studies performed by the laboratory would not be accepted by FDA in support of the investigation. The laboratory permitted inspection; no further regulatory action was necessary.

APPENDIX D

DEPARTMENT OF HEALTH & HUMAN SERVICES

The Administrator
Washington, D.C. 20201

JL 1

The Honorable Claude Pepper
Chairman, Select Committee on Aging
Washington, D.C. 20515

Dear Mr. Chairman:

This is in response to your recent letter requesting the Health Care Financing Administration (HCFA) to provide information on a number of issues involving cataract surgery. The information you requested is as follows.

1. Medicare information by procedure for cataract surgery is currently available for inpatient hospital care only. Information by procedure for physicians' services (recently collected for the first time for 1983 services) is not yet available. Data on procedures for outpatient hospital services are not collected.

   Data for inpatient hospital procedures for DRG 039, Lens Procedure, (includes all cataract surgery) are available for calendar year 1981 and fiscal year 1984.

DRG 039	Number of Cases (000)	Average Charge Per Case
Calendar year 1981	332	$ 1,639
Fiscal year 1984	409	2,344

   Please note these limitations of the data:

   a. Data for fiscal year 1984 is still incomplete due to lags in submissions to HCFA's central statistical processing areas;

   b. Average costs for surgical procedures are not available for 1984. However, we have provided average charges for DRG 039 which encompasses all cataract surgical procedures for both 1981 and 1984.

   c. Similar data for 1982 and 1983 are not available.

2. Outpatient cataract surgery is covered under Medicare. In recent months, attention has focused on outpatient cataract surgery because more and more Utilization and Quality Control Peer Review Organizations (PROs) are screening claims for cataract surgery to assure that they are performed in the appropriate setting. HCFA is in agreement with the PRO review of cataract surgery and closely monitors all of their objectives, activities and the effect on Medicare beneficiaries.

As you know, Medicare review requirements are established by local PROs. The purpose of the PRO program is to assure that the care provided to Medicare patients is medically necessary, is provided in the appropriate setting, and meets professionally accepted standards of patient care quality. In that regard, each PRO must meet certain objectives designed to provide that assurance. One of those objectives is to reduce hospital admissions for elective procedures that could be performed effectively, and with adequate assurance of patient safety, in an ambulatory surgical center or on an outpatient basis.

Medical authorities agree that many lens procedures which are now performed on Medicare patients on an inpatient basis can be safely, effectively, and more economically performed on an ambulatory basis. As a result, over 30 PROs have an objective to shift lens procedures from the inpatient setting to the outpatient setting where that setting is appropriate.

Screening criteria are developed by PRO physicians. They are used by the PRO to approve payment for cases which clearly meet accepted standards and to refer questionable cases to physician reviewers. The PRO physician reviewers, who are actively practicing physicians in the State, make their determinations based on their own knowledge, experience, training, and on discussions with the attending physician for the case being reviewed. In making a determination about the appropriateness of inpatient versus outpatient cataract surgery, the PRO physician reviewer must evaluate all the circumstances which may impact on the medical care in a given case. This involves taking into consideration the medical condition of the patient before surgery, as well as the needs of the patient following surgery and other extenuating circumstances. The screening criteria, however, only apply to elective surgery. Patients with emergencies are always admitted whether or not the PRO has performed its review.

When a denial is made, the PRO program provides a comprehensive reconsideration and appeal process to protect the interest of Medicare patients. The patient, his representative, the hospital, or physician has the right to request a reconsideration if dissatisfied with a PRO's decision.

3. Payment for the intraocular lens (IOL) is not part of the ambulatory surgical center (ASC) facility rate, but rather, is made under the prosthetic device provision. Carriers do have a uniform approach to payment for IOLs which involves application of the Medicare program's reasonable charge principles. These principles involve the calculation of a customary charge and a prevailing charge based on actual charge date of physicians or suppliers. In addition, carriers have discretion to make inherent reasonableness determinations in setting the reimbursement rate for IOLs.

4. A HCFA investigation of available data showed that the vast majority of cataract surgery is performed on either an inpatient or outpatient hospital basis.. The trend is toward one day inpatient surgical stays. Payment for

intraocular lenses is not an issue in these instances. The cost of lenses is included in the DRG for inpatient cataract surgery. When the hospital provides the lenses for outpatient surgery, cost reimbursement is the basis of payment. Although the physician could provide the lenses for outpatient surgery and bill on a reasonable charge basis, this is rarely done. Thus, there is little potential for savings through administrative action by HCFA or its contractors.

5. There is no official HCFA position on the reasonableness of surgeon fees for routine cataract surgery. However, there is concern that certain procedures have become overpriced in relation to the time, effort and risk involved due to the development of new procedures and technologies. HCFA will be contracting for studies to develop a relative value scale on the cost of producing physician services for possible use under current legislative authority or as part of overall physician reimbursement reform.

6. HCFA's policy states that the use of the services of an assistant surgeon in cataract surgery may be considered reasonable and necessary if, for particular medical indications, it is the accepted procedure among ophthalmologists in the local community. The reasonable charge for the services of an assistant surgeon may not exceed 20 percent of the prevailing charge, as adjusted by the economic index, for the surgical procedure. This limitation applies to reasonable and necessary services of assistant surgeons in all settings.

7. The prospective rates of payment for ASC facility services now in use were established in 1982 based on a relatively small sample of the operating costs and charges for services of ASCs in existence at the time. While we believe that the rates are generally appropriate, we also believe there is reason to review the rates to determine whether any changes are indicated by current operating cost data and other fiscal information. HCFA is developing a survey to obtain cost data from all participating ASCs in order to do the review.

8. Nothing in those portions of the Medicare law and regulations which deal with civil rather than criminal matters and for which HCFA is responsible precludes a hospital from routinely waiving payment of deductible and coinsurance amounts for hospital services. Such waiver precludes Medicare payment for the waived deductible and coinsurance as a bad debt but does not otherwise reduce Medicare payments to the hospital. The Office of Inspector General (OIG), however, views such waiver as a possible criminal violation of the bribes, kickbacks, and rebates provisions of section 1877(b) of the Social Security Act. The OIG is currently working toward resolution of this issue with the Department of Justice.

Under the law (section 1833 of the Social Security Act), payments from ASC facility services are not subject to deductible and coinsurance. Also, the payments for the related surgical services by the physician are not subject to the deductible and coinsurance if the physician accepts assignment. (This would also be true if the same surgical services were performed by the physician on an outpatient basis in a hospital.) Thus, no question of a possible civil or criminal violation should arise regarding the provision of "no cost" cataract surgery to beneficiaries in an ASC.

I hope the information we have provided is helpful to you. If I can be of any further assistance, please do not hesitate to contact me.

Sincerely yours,

Carolyne K. Davis

Carolyne K. Davis, Ph.D.

Page 8 BARRON'S October 1, 1984

Cutting Edge of Eye-Tech

A Close Look at IOLs, the Latest Speculative Favorite

By JAYE SCHOLL

LOS ANGELES—Stretched along a wide, hot valley in Southern California is a string of pioneering medical companies which have proven remarkably adept at surviving in a hostile high-tech environment. This 30-mile swath, located to the east of Los Angeles, is the center of the intraocular lens industry. Inevitably, it has been dubbed "IOL Valley."

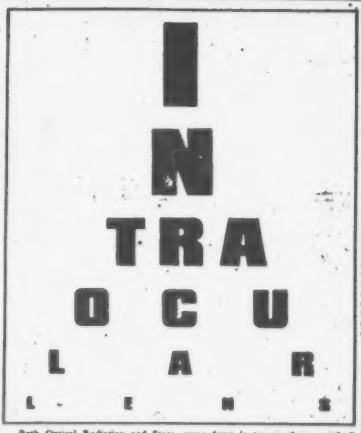
This year, the IOL industry will sell $240 million worth of its lenses. Most will be implanted in the eyes of elderly patients following cataract surgery. Implants are such a popular alternative to wearing either thick-lens glasses or contact lenses that 80% of all cataract procedures now involve IOLs. Demographics suggest the market for IOLs will expand rapidly over the next decade. Estimates are that IOL sales will hit $700 million by 1990, when the number of IOL implants in the U.S. is expected to reach 800,000 per year.

Some 30 companies worldwide manufacture IOLs, but the field is dominated by large medical companies which muscled into the market by acquiring much smaller outfits in the late Seventies. The undisputed leader in IOL sales is Johnson & Johnson's Iolab, which industry watchers reckon sold $60 million worth of the artificial lenses in 1983. (The company does not break out revenues figures for Iolab.) A research report by the securities firm, Hambrecht & Quist, ranked the other major players thusly: second, the Rorer Group's Cilco with IOL sales of $41 million; third, Intermedics with $31 million in sales; American Hospital Supply's American Medical Optics unit was fourth, with sales of $25 million, and Precision-Cosmet, the contact lens company acquired by Frigitronics, with sales of $21 million, fifth.

Positions can shift quickly, though, because this is an industry driven by two forces: innovation and all-out marketing. Then too, for all its high-tech sheen, the barriers to entry are low while the rewards are high, a combination which has persuaded more and more companies to start making IOLs. To stay on top of the heap, the major companies spend an average of 10% of their revenues on research and development. But big R&D budgets alone can't guarantee continued dominance. With just one new lens, much smaller companies have shown they are capable of making a splash.

Prospects for rapid growth and the glamour of "eye-tech" have put IOL companies in Wall Street's speculative spotlight and their shares sell at eye-popping price/earnings ratios. Particularly the "pure plays." Optical Radiation Corp., for instance, while off from its April high of $40 a share, still trades at 32 times its fiscal 1984 fully earnings of $7.85 million, or $1.05 a share. Another "pure play," Storz Surgical, is approaching at a loss, but investors obviously have high hopes for its future.

In recent weeks, the over-the-counter stock has traded for as much as $19 a share and, even after a precipitous fall, is still changing hands around $16.



Both Optical Radiation and Storz have entered a fiercely competitive market with two of the most talked-about lenses in the industry. In 1982, Optical Radiation introduced a lens which blocks ultraviolet light. By 1984, the company's lenses, led by the UV-400 IOL, had captured an impressive 15% of the IOL market.

For its part, Storz Surgical has developed a lens made of silicone. The soft, rubber-like material permits the lens to be folded in half before it is inserted, theoretically requiring a smaller incision in the eye. The foldable aspect of the lens has earned it the name "Mastmove Tone," after its inventor, Dr. Thomas Mastmove of Van Nuys, Calif.

What has wheated Wall Street's appetite for the shares besides an expanding market and that old high-tech magic are the high profit margins on intraocular lenses. The lenses sport $200-$400 price tags, though they cost an average of $40-$60 to make. Many analysts, moreover, cheerfully predict that prices will remain firm or even rise in the years ahead.

Leading ophthalmologists and marketing executives of IOL companies, however, scoff that analysts and investors alike may be peering at the field through rose-colored glasses. The IOL industry, they contend, is beset by pressures to reduce prices because of competition and regulatory forces. As for some of the newer products, those critics contend, they are expensive and may pose unnecessary risks.

"I think the prices and profits will come down in two or three months," predicts Dr. Walter Stark, professor of ophthalmology at Johns Hopkins Hospital's Wilmer Institute and chairman of the Food & Drug Administration's Ophthalmic Devices Committee, the board which approves IOL lenses. "Doctors aren't thinking about the cost of lenses, but hospital administrators are because hospitals are losing money on these procedures."

Depending on local charges, hospitals are reimbursed between $700 and $1,700 by Medicare for cataract procedures. Hospitals are appealing to the Commission on Prospective Payment Assessment to increase the amounts, making the point that the flat reimbursement rate was set in 1981 when only 20% of the cataract procedures involved implanting IOLs. The commission is not expected to make a recommendation until next spring at the earliest, and in the meantime, hospitals are losing money on the operations. In turn, they are pressuring doctors to shop around lively for lenses. "These companies call the same lenses to Europeans for a lot less," points out Dr. Stark.

In fact, price-cutting, down and hard, is already visible. Because of the competition, IOL companies have had considerable sales trouble that have not only prevented a price rise, but may have softened the integrity of the optic (the lens) components in use.

Last December, the [illegible] of the Health Care Financing Administration sent letters to medical insurance companies saying that "it has come to our attention" that "some hospitals owners of intra-ocular lenses and related products are furnishing products to ophthalmologists at no charge in exchange for purchasing their products." The letter cited the anti-kickback provision of the Social Security Act, which forbids hospitals and physicians from accepting free lenses and not reflecting those savings in bills to insurers. A second letter with a similar warning was sent to the IOL companies.

At the most innocent level, companies offer free surgical accessories, called surgical packs, if a doctor or hospital buys one of its lenses. Pharmacia A.B., a Swedish medical company with operations in New Jersey, includes a disposable syringe filled with Healon, a clear liquid which helps maintain the shape of the eye during surgery, and disposable sponges and knives. The pack is worth about $75, according to James Largent, marketing director of Pharmacia's ICL division. Including the pack brings the cost of Pharmacia's IOL down from $325 to $250, he says. Largent adds that it is up to the hospitals or the surgeons to recoup for the savings in their billing.

Hospital administrators, however, are apparently confused about how to deal with these "incentives." And most publicist range from nonchalance to outright refusal to accept them. Richard Norling, for example, administrator of the California Hospital Medical Center in Los Angeles, argues that the notion of accounting for incentives in Medicare billing is "inconsistent" with the goals of the prospective reimbursement system. "We get a flat fee for procedures. The whole point is to do those procedures as cost-effectively as possible. We certainly would not evade kickbacks," he says.

Herb Lyon, administrator of Beverly Hills (Calif.) Medical Center, notes that in return for purchasing CooperVision's IOLs, his hospital gets free surgical packs or a break on the $1,000-a-month leasing fee on its phacoemulsification machines. The latter is a device which uses ultrasonic vibrations to turn cataracts into liquid before sucking out the concoction. He says his hospital doesn't credit Medicare rebates, but instead, gives some of its poorest patients (of which he has many) free IOL implants.

Matthew B. Chamberlain, chief executive officer of Hollywood Presbyterian Medical Center, on the other hand, says that his hospital accepts absolutely nothing for free. "The practice, in my opinion, produces questionable business ethics."

IOL companies also give hospitals expensive equipment such as YAG lasers. The lasers come in very handy if a post-implant problem finds that the capsule around his new lens has clouded up. This thing, which happens about half the time, by bringing the laser on the capsule, the physician can tear a hole in the membrane. Result: the patient's corrected sight from the window, and restores vision. First generation YAG lasers cost between $50,000 and $75,000.

"There's nothing wrong with it as long as the hospital gets the YAG laser."

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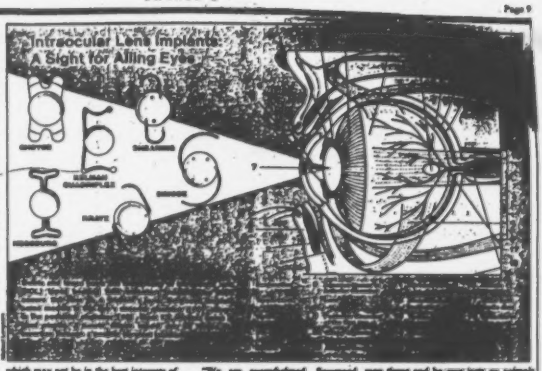
October 1, 1984 BARRON'S Page 9

Intraocular Lens Implants: A Sight for Ailing Eyes



remarks one IOL marketing executive who acknowledges that his company sells IOLs in "packages," sometimes with free surgical kits thrown in, sometimes with sophisticated medical equipment offered as an incentive. "But the problem," he continues, "is the way it's being used. Some of the companies are making deals directly with doctors, i.e., 'if you buy our lens, we will give you personally a YAG laser.'" The fact that cataract surgery, among other procedures, is increasingly being done in doctors' private offices is a trend not lost on the more aggressive companies. Obviously, the doctor becomes a customer to be courted intensely.

David Karcher, executive director of the American Intraocular Implant Society, based in Santa Monica, Calif., takes a very stern view of any form of discount which cannot be reflected in bills. "Here is a hospital supposed to collect a YAG laser when they're getting reimbursed for a flat fee?"

At a minimum, the "incentives" being offered suggest the degree of elasticity in the prices of IOLs, a factor which will presumably be taken into consideration when the Commission on Prospective Payment Assessment reviews the fee for cataract surgery.

As for offers to surgeons, Karcher said he is well aware of the problems of kickbacks in the IOL business. "I get calls all the time from doctors who asked me if they can accept a YAG laser. I tell them, 'Try for the damn thing yourself.'" He says physicians also asked whether they can accept free surgical packs. "Our position is that any savings to a hospital or a doctor must absolutely be reflected in their bills."

The scenario bears a disturbing resemblance to the cardiac pacemaker industry of recent years, and not surprisingly, the analogy is made often by both doctors and executives. Some of the earliest pacemaker salesmen, in fact, also were full intraocular lenses. While no one has suggested that the IOLs are defective, as some pacemakers have proved to be, concerned observers worry that physicians have been hustled, coaxed and/or cajoled to make decisions which may not be in the best interests of their patients.

Responding to advances in medical technology, for example, physicians are recommending corrective surgery at earlier stages of cataract disease. "You used to wait until you were stone blind," as one surgeon put it. "A lot of patients don't want to wait that long." But there is growing worry that some physicians don't want to wait that long, either.

"I can't believe that the number of operations going on can be attributed solely to the aging population," remarks Dr. Robert Cohn, chief of ophthalmology at Lenox Hill Hospital in New York. Two weeks ago, he says, he gave a second opinion to a "flaming dinosaur" scheduled for an IOL implant last Wednesday. "I can read. I can do everything," the patient told Dr. Cohn. After examining her eyes, he agreed. The operation was cancelled.

At present, some 30 "models" of intraocular lenses have completed the tortuous approval path mapped out by the Food & Drug Administration. Another 350 or so modifications to those "parent" models are in various stages of approval, but because of a 1976 ruling, these lenses are available to surgeons under the FDA's investigational device exemption (IDE).

With the IDE, lens manufacturers line up physicians around the country who are willing to implant a company's new lens and keep extensive records on their patients' progress. Before the FDA grants approval to market a completely new lens, the company must submit records on at least 500 new implants. Modified lenses, which use proven materials, require about 100 tests.

Because of swift changes in the industry, both in terms of technology and fashion, IOLs quickly become outdated. "It's like lenses," quips Dr. Cohn, who adds that many of the 400 lenses available are "lenses." The absence of a clearly superior lens, coupled with the prospect of enormous profit margins, has created a free-for-all among lens manufacturers. In the Rockville, Md., offices of the Food & Drug Administration, at least 300 additional lenses are awaiting the agency's imprimatur.

"We are overwhelmed. Personnel isn't the issue for it," admits one of the FDA's reviewers. Because of budget cuts and the demand of applications, reviewing the contents of any patient is backlogging a year or more. "The staff is in no way able to keep up," he says.

Until now, the short but explosive life of the IOL industry has been dominated by hard lenses made of a plastic called polymethylmethacrylate, or PMMA. The use of PMMA dates to the Thirties, when Royal Air Force surgeon Harold Ridley observed that shards of plastic from exploding fighter plane windscreens remained inert in pilot's eyes. Though the leap to using PMMA for artificial lenses was swift—Dr. Ridley implanted the first PMMA lens in 1949—the evolution of surgical approaches has been circuitous. At first, ophthalmologists inserted artificial lenses behind the iris, then in front of it, and since the mid-Seventies, again in back of the iris.

Today, the most common procedure is the extracapsular extraction, or ECCE, in which surgeons remove the portion of the lens located behind the iris. Although many surgeons prefer ECCEs can be done with a small smaller incision in the eye.

As technology have advanced, however, Dr. Ridley's observations had remained constant. PMMA remained the ne detrimental effects on the eyes, even after 40 years. No matter how cute corneas, long lens materials ultimately prove to be, it will be years before they are ready for or surpassing in them the PMMA.

That hasn't stopped companies from trying, however. Following an implant procedure, for example, Allergan Humphrey had to withdraw from the market a green silicone on the outside of its new flexible lens with the brandname, "O Wonder," and pictured Dr. Johnson as saying, "Silicone appears to be the ideal lens-compatible material for IOLs."

"You have to take green tinted sunglasses & gallon of milk," commented Dr. Ridley soon, "but we found 8% one of the best lens-compatible materials we use."

Manufacturers' patents and their claims of a 25-year history of using silicone in lens

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REENTRY INTO GROWTH

Continued from Page 23

ellites and cable, it doesn't do the job very vigorously and the deregulators at the commission have said they'd like to drop it altogether when competitive conditions permit. That could pose a problem, since AT&T plans to lay its first expensive fiber optic cable for service in 1988.

As if competing against AT&T wouldn't be enough, U.S. telecommunications companies, such as Western Union and RCA, might PCC permission to deal directly with Intelsat, bypassing Comsat.

To take it further, if competing against all its existing customers wouldn't be enough, two new companies, Orion Satellite Corp. and International Satellite Inc., are clamoring to build their own transatlantic satellites to compete against Intelsat. There would be a common business Intelsat charges reporting a system-wide average, which means the big-volume transatlantic routes are kept high to subsidize low-volume services elsewhere in the world. Competitors would be under no such restrictions.

If all these proposals went through, Comsat's international monopoly would be destroyed. All its customers would be competitors and its supplier would be embattled ex-prexy.

Happily for Comsat, things are looking up on two of the three competitive international fronts. In April, the FCC passed a ruling letting U.S. carriers deal directly with Intelsat, preserving the Comsat monopoly. Intelsat has been conducting a diplomatic lobbying campaign against them would be rivals that seem to be taking hold.

Even the competition from the AT&T cable looks no more threatening than it did. FCC officials indicate they expect to keep regulation at least in part; they will not allow AT&T to engage in predatory competition.

One measure of the commercial competitiveness of the Intelsat system is the way Comsat keeps bumping up against the IntelSat allowable rate of return, bringing FCC-mandated rate cuts. The latest one was a 5.9% decrease July 31, which Comsat's critics greeted with a groan-like that it would hit earnings for about 40 cents; more properly, they should have said up a cheer for the strength of one of the company's vital signs.

In sum, despite Wall Street's current skepticism, the picture at Comsat has brightened considerably, thanks to elimination of the continuing losses at SBS and continued strength in the monopoly businesses. Not to be overlooked, either, is renewed vigor in Comsat's U.S. domestic satellite business and promise of profitability in 1985 in the data-comm businesses that have been a 30-cent to 50-cent a share pretax drain for several years. And, who knows? One or two of Comsat's more speculative ventures might get lucky on just one of those years as well. ■

CUTTING

Continued from Page 9

an aggressive securities firm, as one of its market makers. As readers of Barron's know, First Jersey Securities has been acquired by the Securities and Exchange Commission of over-the-counter stocks.

"They're making a makeover of themselves," says Thomas Waggener, president of Bauer Surgical, but as he points out, there are at least five other market-makers in Bauer, the presence of whom [illegible] Jersey's influence.

Waggener says [illegible] tion with Kidder, [illegible] additional financing [illegible] ting, and that he [illegible] commitment" for [illegible] other sources. "We've had to scale back and postpone a couple of things, but I can smell break-even," he confides.

If break-even is in the offing, it won't be from sales of the elastic lens, which are at least two years away from receiving full FDA approval. "If it works, I expect there will be a lot of 'me too' products," says Waggener, "but we'll have at least a six-month headstart." Bauer has two patent applications pending for its lenses, but even Waggener downplays their importance. "To be honest, patents are not worth much."

In the meantime, Bauer is pursuing related businesses. It has developed a conventional PMMA lens, a phacoemulsification machine, which uses ultrasound vibrations to remove clouded lenses, and disposable surgical kits used during IOL implants. "We're tight," is the way Waggener described his company's cash situation, "but we don't need money to survive, just to expand."

But in each of these markets, Bauer faces stiff competition. Johnson & Johnson's Iolab Corp. Group's Cilco division, Pharmacia's Medical Worldwide, Pilgrimedics' Precision-Cosmet and American Hospital Supply's AMO are just some of the companies making PMMA lenses, for example. A number of these companies report that they are working on three-millimeter lenses as well.

In addition to companies, surgeons themselves are developing new lenses. Dr. Charles Kelman, inventor of the aforementioned phacoemulsification process and considering of a transfection in the IOL world, claims that he has developed a three-millimeter lens, and that it

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CUTTING EDGE

Continued from Page 26

will be available to surgeons for test implanting by spring, Kelman, who already has a bunch of IOLs bearing his name, says his lens is made of PMMA. Using a proven plastic material will be the key, he believes, to rapid acceptance in the marketplace, not to mention an easier path to FDA's approval.

Because of the shifts in IOL preference, companies with a new product can quickly establish a market presence. Thus, Optical Radiation took the industry by surprise with its introduction of the first ultra-violet absorbing lens. Using a material which is bonded to PMMA, the lens blocks 99% of the ultra-violet light.

To patients whose natural lenses were about to be removed, Optical Radiation's UV blocker was an instant hit. For the first time, surgeons had patients demanding a particular brand of IOL. Spurred by the success of the lens, Opticol, which is into various other eye-tech and high-tech products, saw revenues zoom from $18.3 million in fiscal 1982 (ended July) to $26.6 million in fiscal 1983 and $48.2 millions last fiscal year. Earnings per share shot up from 21 cents in fiscal 1982 to 47 cents the following year and $1.05 in fiscal 1984, or some 120% over last year.

Because of the clamor over UV lenses, other companies swiftly set about developing their own—Ciba, Iolab and American Medical Optics, among them. Wedged between this battle for UV market share, however, are the surgeons, many of whom say they buy UV lenses because their patients ask for them, not because they believe in them.

For despite the publicity and the claims made for UV lenses, there is no medical evidence—just a lot of opinions—that ultraviolet light damages the eye's retina, according to Dr. Stark, chairman of the FDA's Ophthalmic Devices panel. Even IOL companies executives question the validity of the concept. "The whole UV business is marketing hype," concedes one director of an IOL division, who adds that his company nevertheless introduced just such a lens to thwart the competition.

Even if the competition has already cut into Optical Radiation's share of UV lens market, its dominance is such that most analysts predict continued increases in sales through 1985, and possibly an even greater share of the UV market. But Optical Radiation, like its rivals, will face additional pressure to reduce the prices of its lens, not only from regulators, but from an inevitable slowdown in the growth of the market.

Whereas five years ago only a quarter of cataract operations used IOL implants, today that figure is over 80%. The growth has clearly been explosive. But just as clearly, there is a limit. Most doctors reckon that the market will increase to a maximum of 95% of all cataract operations within two years. But from that point on, old competition and new entrants alike will be splitting a market whose growth will largely be determined by demographics. Some opportunities exist in selling more lenses abroad, but as mentioned, the price of IOLs in Europe is about half of the U.S. price.

In fiscal 1983, IOL sales accounted for about one-third of Optical Radiation's revenues. The acquisition of Omega Optical, a leading laboratory processor of ophthalmic lenses could dilute that contribution this year. In 1985, its fans estimate, Optical Radiation should earn $1.60 a share, and $3 in '86.

Amid all the excitement over ultraviolet light blockers and three-millimeter lenses, however, some physicians are taking a much more jaundiced view. Dr. Stark, for one, says he reacts "very, very cautiously" to these new developments.

"Modifications have often led to serious problems. Some IOLs have been taken off the market. What concerns me is the addition of new substances to lenses." No one knows, he says, whether the material added to lenses to make them block ultraviolet light will prove safe, as far as he is concerned the advantages do not outweigh the risks.

"New things are nice to talk about, but if you put [UV blockers] in the eyes of young people 30 to 40 years old," observes Stark, "you have to look at it very cautiously. Ultraviolet light can be blocked by glasses, which is what I'd rather wear."

As for three-millimeter lenses, he's of the opinion that while they may be innovative, they don't offer a great benefit. "Whether it's a three-millimeter or five-millimeter incision makes no big difference. We're not having problems treating the wound." And, he adds, there are also no problems with ultraviolet light. "It really irritates me. Basically, doctors with a financial interest read the companies are behind it. It's a big promotional thing."

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APPENDIX E

July 30, 1984

TWENTY MILLION PEOPLE IN UNDER-DEVELOPED NATIONS ARE BLIND FROM CATARACTS. THESE MILLIONS CAN SEE AGAIN WITH SURGERY AND AN I.O.L.

Dear Doctor,

Can you imagine never seeing your children or grandchildren? If you were in this condition what would you give to be able to see again? Many of us desire to help but we need direction.

has given thousands of lenses away per year for the needy. We need to do more. These are our ideas;

#1. For every lens implanted and paid for by your clinic or hospital, will fund up to eighty dollars per lens (amount depends on whether your clinic or hospital receives a volume discount). These funds can be directed to your church, SEE (Surgical Eye Expeditions), Orbus, or directly to a foreign clinic for surgical microscopes, drugs, air fares for you to fly to these places to operate and instruct, or for whatever charity you decide upon. will also provide I.O.L.s at no charge.

#2. If you desire to use another brand of I.O.L.s in your clinic, we will still give you I.O.L.s for any overseas philanthropic endeavor.

If only two hundred doctors in the U.S.A. become partners with us in this work we can fund the free eye clinics over $1,000,000. per year.

#3. If a poor patient in the U.S.A. is not covered by medicare or any health program, will provide a lens at no charge, upon request. If you will do the surgery at no cost.

If you desire more information, please call the Chairman of Charities, Mr.

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, 1984

' Hospital

Dear

In response to your phone call earlier today, I have revised our , 1984 proposal to Hospital l to reflect an anticipated increase in implant volume from your hospitals. The new bid proposal includes the intraocular lens styles listed below:

Lens Style	Chamber	% Discount	Discounted Price/Lens (True Price)		(Non Contract Price)
	Anterior	58%	325.00	$138.00	163.00
	Anterior	58%	325.	$138.00	163.
	Posterior	58%	325.	$138.00	163.
	Posterior	58%	325	$138.00	163.
	Posterior	58%	325	$138.00	163
	Posterior	58%	325.	$138.00	163
	Posterior	58%	350.00	$147.00	175.00
	Posterior	58%	375.00	$158.00	188.00
	Posterior	58%	375.00	$158.00	188.00
	Posterior	58%		$158.00	
	Posterior	58%		$158.00	
	Posterior	58%		$158.00	
	Posterior	58%		$158.00	

This bid proposal was prepared using a revised volume projection of 125 intraocular lens implants/month. Should the total average monthly implants change significantly from this projection, the discounted prices will be reviewed and adjusted according to the attached schedule. An initial three month grace period will be permitted for Hospital members to allow these hospitals the opportunity to become familiar with intraocular product line and increase their usage of our lenses.

At the risk of being redundant, I have again listed the various services that your member hospitals will receive from at no additional charge:

- o FREE IN-SERVICE TRAINING WITH CEU credits awarded.

[illegible], 1984

- o NO RESTERILIZATION CHARGE.
- o LOCAL SALES REPRESENTATIVE on call 24 hours a day.
- o INITIAL CONSIGNMENT INVENTORY shipped and set up at no charge.
- o [illegible] - CONSIGNMENT INVENTORY MANAGEMENT SYSTEM, to simplify the record keeping and reordering of IOL's.
- o FREE PATIENT INFORMATION BROCUHRES that explain cataracts and IOL's to your patients.
- o EXPANDED CUSTOMER SERVICE HOURS to better serve your needs. (4 a.m. to 5:30 p.m. PST)
- o ALL PMMA LENS CONSTRUCTION for quality and durability.
- o BLUE PMMA LOOPS for improved visibility by the surgeon during implantation of a lens.

The completion and return of this letter indicates your acceptance of this bid proposal and places the above prices in effect as of the date indicated. The expiration date of this discount agreement will be twelve months from the effective date below and is based on remittance Net 30 days.

Pamela, I appreciate the opportunity of discussing [illegible] Hospital [illegible] specific circumstances with you and look forward to a long working relationship with you and your organization. If you require any further assistance pertaining to this revised bid proposal, please do not hesitate to contact me at 1-800-[illegible].

Sincerely,

DISCOUNT PRICE SCHEDULE

# Implants/Month	# Implants/Year	% Discount
0-4	0-48	10%
5-12	49-144	15%
13-25	145-300	20%
26-42	301-504	25%
43-63	505-756	30%
64-83	757-996	40%
84-124	997-1488	50%
125+	1489+	58%

Dear Doctor:

Ophthalmic outpatient surgery centers are being developed at an astonishing rate. It is estimated that 80% of all ophthalmic surgery will be performed on an outpatient basis by 1987.

Have you ever wondered if an outpatient center is in your future?

Answering that question could be simpler than you think. A leading consulting firm has developed a sophisticated new software program that can generate a financial feasibility study and projected income/cash flow analysis based on your current practice and surgical volume.

All you have to do is provide the input.

There's a questionnaire on the back of this letter. Simply fill it out and mail it directly to [redacted] Corporation. They'll send you an analysis plus a computer generated floorplan of one way your surgery center might look.

This service is underwritten by [redacted] to help surgeons evaluate the direction of their practice. There is absolutely no cost or obligation to you. Please feel free to avail yourself of this information.

Sincerely,

Ophthalmic Outpatient Surgery Center
Feasibility Analysis

Physician Questionnaire

Physician's Name (LD) Address

Telephone City State Zip

To receive a computer generated feasibility analysis of an ophthalmic surgery center for your practice, please complete the following questions.

A. Percentage of your cataract extractions utilizing the following techniques: KPE 10 %
ECCE 88 % ICCE 2 %

B. Percentage of your cataract patients receiving an IOL: 95 %

C. Brands of equipment and disposable packs currently used:
PEA (Phaco) unit Coopervision Phaco pack Cooper - Cavitron
I/A unit Cavitron I/A pack Cavitron

D. Percent of your IOLs: ACL 2 % PCL 98 % UV 100 %

E. Type of ambulatory facility contemplated:
Office Based 75 % Free Standing 25 % Hospital Affiliated ____ %

Fill in as many actual factors as possible. Assumed factors will be applied where actuals are omitted.	Assumed Factor	Actual Factor
1. Number of IOLs you (and your associates) implant each month.	20	45
2. Percentage increase in implants you are projecting after opening an ambulatory surgery center.	40%	60
3. Medicare facility fee for cataract extraction with IOL.	$ 530	$
4. Your Medicare surgical profile fee per case.	$ 2,000	$ 2075
Assistant's fee is 20% of profile (enter 0 if none).	$ 400	$
5. Number of cataract cases performed per surgery day.	5	4-7
6. Contract personnel		
R.N. circulator required)	$ 130/day	$
Surgical technician	$ 30/case	$ ✓
General purpose person (usually available from existing staff)	$ 0/day	$
Full time employees		
R.N. circulator @ $2,500 per month	$ 0	$
Surgical technician @ $1,800 per month	$ 0	$
General purpose person @ $1,500 per month	$ 0	$
7. Equipment for facility with one O.R. without phaco unit (enter $170,000 for two O.R.'s).	$110,000	$
Additional cost with each phaco unit $40,000.	$ 0	$
8. Building lease per square foot per month.	$ 1.25/mo	$ 1200
9. Space preferred for a facility with ONE O.R. (enter 1,500 for TWO O.R.'s).	1,200 sq ft	1500
10. Percentage of time a visco-elastic agent is used.	10%	100%

Please return the completed questionnaire to:

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, 1984

, M.D.

Dear Dr.

Thank you for returning the questionnaire regarding the financial feasibility of developing your own outpatient surgery center. We believe the resulting enclosed documents will greatly assist you in your planning since they do reflect your personal situation.

The assumptions used to create the income statement and cash flow schedule reflect current construction and supply costs, costs of capital and federal reimbursements.

The analysis is conservative in that it reflects only cataract cases with implant and a small percentage of other procedures reimbursed under Medicare. Perhaps the addition of a laser room and the acquisition of YAG and argon lasers would make such a proposition even more attractive.

You will find the analysis generally self-explanatory but please feel free to call if you have any questions or would like to approach it from, perhaps, a different angle.

We would like to hear from you to further explore the development of your own ambulatory surgery center. Contact any one of our corporate officers: or me.

Sincerely,

President

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SURGICENTER FINANCIAL FEASIBILITY ASSUMPTIONS

1. The number of cataract procedures with implant you and your associates) perform each month.			45
2. The POTENTIAL percentage increase in surgical volume you can expect after opening your own surgicenter.			60 %
3. The MEDICARE facility fee for ECCE with IOL in your area.		$	530
4. Your MEDICARE surgical profile fee per case.		$	2,075
Assistant's fees @ 20% of profile.		$	415
5. The number of cases performed in a day of surgery.			5
6. Contract personnel			
R.N. circulator (required)		$	130 per day
Surgical technician		$	30 per case
General purpose person (usually available from existing staff)		$	0 per day
Full-time employees			
R.N. circulator @ $2,500 per month		$	0 per month
Surgical technician @ $1,800 per month		$	0 per month
General purpose person @ $1,500 per month		$	0 per month
7. Complete equipment package for facility with ONE O.R. including microscope and I/A machine ($170,000 for TWO O.R.s)		$	170,000
Phacoemulsification unit (add $40,000 each)		$	0
Equipment lease factor per thousand $ per month			23.48
8. Building lease rate		$	1.00 /sq ft/mo
9. Surgicenter space preferred for ONE O.R. (1,500 for TWO O.R.s)			1,500 sq ft
Capital improvements		$	50 /sq ft
Total cost of improvements in existing shell		$	75,000
Down payment percentage			0 %
Total down payment		$	0
Amount subject to permanent financing		$	75,000
Interest rate (10 year term)			14 %
10. Visco-elastic agent	Percentage of cases used 100 %	$	60 /case
11. Property taxes as a % of construction cost			1.25 %/yr
12. Disposable surgical packs		$	80 /case
13. Disposable I/A or phaco packs		$	50 /case
14. Medications		$	50 /case
15. Insurance (property & liability)		$	100 /mo
16. Maintenance ($.25/mo/sq ft)		$	375 /mo
17. Utilities ($.25/mo/sq ft)		$	375 /mo
18. Start-up capital (SDC fee & 2 months expenses)		$	51,807

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FUNCTIONAL

Page 7

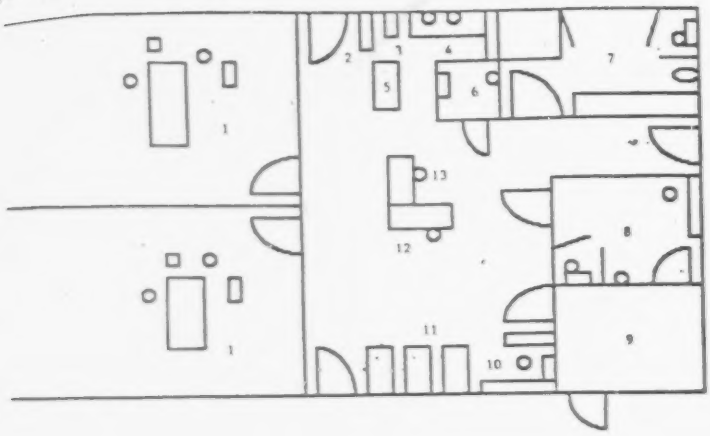
, M.D.

Foreseeable 1988 Vol

BRICKYARD INCOME STATEMENT AND CASH FLOW PROJECTION

		Month	Year	Month	Year
VENUE PROJECTION					
Cataract cases with IOL	Number of cases	65	560	72	804
Income from facility fees	$	23,850 $	196,290 $	26,160 $	337,920
Other facility fees (net)		1,850	21,600	2,850	33,600
TAL REVENUE	$	25,650 $	217,890 $	28,910 $	371,520
PENSE PROJECTION	Number of salary days	0	198	24	270
Contract personnel	$	2,124 $	39,240 $	4,932 $	68,340
Full-time employees (+ 25% benefits)	$	0	0	0	0
Equipment lease		3,842	43,800	3,842	43,800
Building lease		1,500	18,000	1,500	18,000
Loan on capital improvements		1,154	13,845	1,154	13,845
Property taxes		0	900	0	900
Disposable surgical packs		3,400	43,200	3,240	44,220
Disposable I/A or Phaco packs		2,250	27,000	2,400	43,200
Medications		2,250	27,000	3,000	43,200
Visco-elastic agent		2,700	32,400	4,320	72,840
Insurance (property & liability)		100	1,200	100	1,200
Maintenance		375	4,500	375	4,500
Utilities		375	4,500	375	4,500
TAL EXPENSE	$	17,970 $	259,842 $	28,990 $	368,748
H FLOW	$	4,747 $	58,938 $	53,920 $	102,772
Less depreciation (Corp/Other, equip/Tax 413		3,438	41,500	3,438	41,500
COME BEFORE TAX	$	1,298 $	15,438 $	7,696 $	92,272
Income tax expense (benefit) @ 32%			5,726		29,537
Investment tax credit			17,000		
T INCOME	$	24,724		$	57,837
Add depreciation			41,500		41,500
Deduct start-up capital			72,867		
H FLOW after TAX	$	16,633		$	97,337
TAGE FROM POTENTIAL INCREASE IN REVENUE VOLUME				$	49,134 $ 446,362

SURGICENTER FLOORPLAN, 2 O.R.'S, 1500 SQ FT.



HIS SURGICENTER CONTAINS APPROXIMATELY 1500 SQ FT AND THE
OLLOWING AREAS:

. TWO OPERATING ROOMS
. SCRUB
. AUTOCLAVE
. CLEAN-UP
. STERILE SUPPLIES
. JANITOR'S CLOSET
. STAFF CHANGING
. PATIENT CHANGING
. PATIENT WAITING
. RECEPTION
. PRE-OP, RECOVERY
. DICTATION
. R.N. STATION

MEDICARE REQUIREMENTS FOR CERTIFICATION
INCLUDE:

A) STATE LICENSING REQUIREMENTS
B) STATE FIRE MARSHAL REQUIREMENTS
C) STATE BUILDING CODES FOR A.S.C.'S
D) HANDICAPPED FACILITY LAWS WHERE APPLICABLE
E) H.C.F.A. REQUIREMENTS FOR A.S.C. SURVEY

FOR ASSISTANCE IN PLANNING, CONSTRUCTING AND EQUIPPING YOUR
SURGICENTER, CONTACT:

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LENS PURCHASE
AGREEMENT

Based upon your commitment to purchase a total of _____ lenses from _____ for one year, we agree to discount our list price in effect at the time of the order. The last page of this agreement outlines the current discounted bid pricing.

If, after reading the terms herein, this agreement is acceptable to you, please sign where indicated below and include your purchase order number (or attach a copy thereof) and return to Sales Administration Manager for institution of this pricing. This quotation will expire if not accepted on or before October 11, 1984.

Terms of Sale: Shall be 1 in 30 days, net in 60 days.

Minimum Order Requirements: Lenses may be ordered in any quantities. No minimum orders exist as long as agreed purchase volumes are met. Failure to purchase the agreed quantity will result in, (a) a smaller discount percentage or (b) termination of the entire agreement.

Lead Time: Orders will be processed the same day received or as soon as possible thereafter.

Pricing Guarantee: All discounts are from current list prices. If during the term of this agreement, the list prices of _____ fluctuate, the discount will apply to the new list prices. Any price protection clause in effect as the result of a previously executed Consignment Agreement or Addendum becomes void at the time this agreement is executed.

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Lens Purchase Agreement
Page 3

The following is a list of items covered by this agreement:

MODEL	CURRENT LIST PRICE	CURRENT BID PRICE
	$325.00	$260.00
	$325.00	$260.00
	$325.00	$260.00
	$325.00	$260.00
	$325.00	$260.00
	$325.00	$260.00
	$325.00	$260.00
	$325.00	$260.00
	$325.00	$260.00
	$325.00	$260.00
	$325.00	$260.00
	$325.00	$260.00
	$325.00	$260.00
	$325.00	$260.00
	$350.00	$280.00
	$325.00	$260.00
	$325.00	$260.00
	$325.00	$260.00
	$325.00	$260.00
	$325.00	$260.00
	$350.00	$280.00

Lens Purchase Agreement
Page 4

The following is a list of items covered by this agreement:

MODEL	CURRENT LIST PRICE	CURRENT BID PRICE
	$325.00	$260.00
	$350.00	$280.00
	$350.00	$280.00
	$350.00	$280.00
	$350.00	$280.00
	$350.00	$280.00

Thank you for your support of [redacted]. We are pleased that you are interested in our hardware promotional program. As you know, under the program, we would agree to provide you with a piece of equipment in connection with your purchase of our intraocular lenses.

Recently, a number of ophthalmologists received copies of a legal opinion issued by the firm of Leighton, Conklin, Lemov, Jacobs and Buckley to the American Intra-Ocular Implant Society regarding the legality of discounts or rebates on intraocular lenses. It is their opinion that:

1. There is no violation of law in acceptance of intraocular lens discounts, rebates or bonuses by implant surgeons when analyzed under the Social Security Act or under the Food, Drug and Cosmetic Act; but that

2. Intraocular lens discounts, rebates or bonuses must be passed on to third party payers in the Medicare or Medicaid programs when the implant surgeons seek reimbursement; conscious failure to do so may be considered a criminal felony.

Some of our customers have asked how this opinion relates to our hardware promotional program. Our legal counsel has reviewed the program in detail and agrees with the opinion issued by the Leighton firm that it is permissable to participate in discount or similar programs, but that such benefits should be passed on to third party payers in the Medicare and Medicaid programs.

The mechanics of third party reimbursement vary so widely from one ophthalmic practice to another that it is difficult for us to provide specific guidelines as to how the benefit of our hardware program should be reflected in reimbursement claims. Specific treatment should be discussed with your accountant.

We hope this letter will clarify the nature and status of our program. If I may answer any questions or be of any service, please call. Again, thank you for your support of [redacted].

Sincerely,

[redacted]

IOL Marketing Manager

Three Year Purchase Agreement

Intraocular Lenses/Ophthalmic Hardware

M690 M114 Microscope

revised

For Assistance Call:
800-526-0355
or
800-343-0577

WILD OPERATING MICROSCOPE WORKSHEET

Prepared for:
DR
TX
Phone

Prepared by:
SALES REPRESENTATIVE
Phone

NOTE: Boldface Stock Numbers are for M690 Only.

	Stock #	Description	Price	Quantity	Ea Price
Optics Carriers	185 411 571	M690 Optics Carrier	$12,110		
	185 411 571 UV	M690 Optics Carrier with UV Filter	12,139	1	
	185 399 733	M650 Optics Carrier	4,302		
	185 399 733 UV	M650 Optics Carrier with UV Filter	4,331		
Microscope Carriers	185 997 197	S-Y Coupling, M690	$ 7,569		
	185 411 574	M690 Microscope Carrier with inclining lever	1,369		
	185 411 579	M690 Microscope Carrier with Drive	1,895	1	
	185 399 734	M650 Microscope Carrier with inclining lever	913		
	185 399 735	M650 Microscope Carrier with Drive	1,370		
Tiltable Joints	185 182 529	Tiltable Joint with infinitely variable brake	$ 781		
	185 399 785	Tiltable Joint with Drive	1,589	1	
	185 397 487	Counterweight	139		
Stands	185 411 570	M690 Floorstand, MS-C, Rollable	$11,583	1	
	185 433 084	Ceiling Mount, MS-F, for M690 (115 V)	28,486		
	185 415 963	Wall Stand, MS-A, for M690	10,530		
	185 399 783	M650 Floorstand, MS-C, Rollable	7,038		
	185 399 781	M650 Wall Stand, MS-A	6,073		
	185 399 784	M650 Table Stand, MS-D	1,863		
	185 997 194	Column Extender, 8 Inches (For Floorstands Only)	900		
	185 997 193	Column Extender, 6 Inches (For Floorstands Only)	399		
Binocular Tubes	185 382 650	Inclined Binocular Tube, tilter, with iris diaphragm	$ 1,866	1	
	185 384 684	Straight Binocular Tube, with iris diaphragm	1,807		
	185 399 587	Inclined Binocular Tube, tilter angle	1,639		
	185 399 588	Straight Binocular Tube	1,611		
	185 249 903	Inclined Binocular Tube, high angle	940		
	185 182 503	Inclinable Binocular Tube	4,999		
	185 404 005	Double Iris Diaphragm	257		
Eyepieces	185 384 010 *	Eyepieces, 10X/21B	$ 201	2	
	185 334 830	Eyepieces, 15X/14B	448		
	185 377 509	Eyepieces, 20X/11B	455		
	185 399 170	Spacer Ring, 6mm	0		
	185 399 171	Spacer Ring, 9mm	0		
Objective Lenses	185 408 842	Objective Lens f= 100mm	$ 798		
	185 997 174	Objective Lens f= 160mm	475		
	185 997 175	Objective Lens f= 175mm	360		
	185 382 160	Objective Lens f= 200mm	315	1	
	185 407 743	Objective Lens f= 250mm	211		
	185 382 166	Objective Lens f= 300mm	295		
	185 997 176	Objective Lens f= 330mm	452		
	185 382 172	Objective Lens f= 400mm	364		

Total Page 1: 30066
Total Page 2: 2706
Quotation Total: 32,772

Date

9% TAX + SHIPPING

In Response To DRG-39

offers the

D. R. G. Program

combining Cataract Surgical Supplies

- **I.O.L.'s**

  Complete line of the state-of-the-art lenses

- **I/A Kits**

  CooperVision compatible

Free ™ **Balanced Salt Solution**

The standard for years

- **One Year Price Guarantee**

Information Available Upon Your Request

Technology • Quality • Service